[The following redline/strikeout revisions to Appendix C reflect the changes to 10 CFR 35.2 and 35.433 adding an Associate Radiation Safety Officer and the ophthalmic physicist in 10 CFR 35.433; the change to 10 CFR 35.65 to prohibit bundling of single sources; changes to 10 CFR 35.57 grandfathering individuals that were board certified by boards prior to October 24, 2005 by the Boards listed in 10 CFR 35.57; changes to 10 CFR 35.50, 35.51, 35.55, 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, and 35.690 revising the preceptor attestation requirements and the preceptor attestation statement; changes to 10 CFR 35.50 training and experience pathways; and the change to 10 CFR 35.12 describing information needed for 10 CFR 35.1000 medical uses.]

APPENDIX C

License Application Checklists

License Application Checklists

This Appendix contains checklists that may be used to assist in organizing an application. It addresses information a medical use licensee needs to provide for authorization to produce PET radioactive drugs for noncommercial transfer to consortium members. See Appendix AA for additional information.

Table C.1, Applicability Table, may be used to determine if particular information must be provided or if "N/A" (not applicable) may be the response to each item that follows. To determine those items to which applicants must respond, "highlight" the columns under the categories of materials requested in Item 5 (e.g., 10 CFR 35.300, 35.400). If any "Y" beside an item is highlighted, applicants must provide detailed information in response to that item. If the letters "N/A" are highlighted, applicants may respond "N/A" on their applications. If any "N" beside an item is highlighted, no information in response is required, but NRC regulations that apply to the given category apply to that type of license. If any "P" beside an item is highlighted, applicants should provide a commitment as described in the section referenced in the body of this document. If any "G" beside an item is highlighted, see subsequent sections for required responses. "APP" indicates that this document contains an appendix that addresses the item.

Table C.1 Applicability Table								
Section #	**Topic**	**35.100/200**	**35.300**	**35.400**	**35.500**	**35.600**	**35.1000**	**APP**
8.5	Unsealed Byproduct Material – Uptake, Dilution, Excretion, Imaging, and Localization Studies	Y						
8.5	Unsealed Byproduct Material – Written Directive Required		Y					
8.5	Manual Brachytherapy			Y				
8.5	Sealed Sources for Diagnosis				Y			
8.5	Teletherapy Units					Y		
8.5	Remote Afterloader Units					Y		
8.5	Gamma Stereotactic Radiosurgery Units					Y		
8.5	Other Medical Uses						Y	
8.6	Sealed Sources and Devices	N	N	Y	Y	Y	Y	
8.7	Discrete Source of Ra-226 (Other than sealed sources)	Y	Y	N	N	N	Y	
8.8	Financial Assurance Determination	Y	Y	Y	Y	Y	Y	
8.9	Purpose(s) for Which Licensed Material Will Be Used	Y	Y	Y	Y	Y	Y	
8.10	Training and Experience	G	G	G	G	G	G	

Table C.1 Applicability Table								
Section #	**Topic**	**35.100/200**	**35.300**	**35.400**	**35.500**	**35.600**	**35.1000**	**APP**
8.11	Radiation Safety Officer (RSO) and Associate Radiation Safety Officers (ARSOs)	Y	Y	Y	Y	Y	Y	I, D
8.12	Authorized User(s) (AUs)	Y	Y	Y	Y	Y	Y	D
8.13	Authorized Nuclear Pharmacist (ANP)	Y	Y	N/A	N/A	N/A	Y	D
8.14a	Authorized Medical Physicist (AMP)	N/A	N/A	Y*	N/A	Y	Y	D
8.14b	Ophthalmic Physicist	N/A	N/A	Y*	N/A	N/A	N/A	D
8.15	Facilities and Equipment	G	G	G	G	G	G	
8.16	Facility Diagram	Y	Y	Y	Y	Y	Y	
8.17	Radiation Monitoring Instruments	Y, P	Y, P	Y, P	Y, P	Y, P	Y, P	K
8.18	Dose Calibrator and Other Equipment	P	P	N/A	N/A	N/A	P	
8.19	Therapy Unit - Calibration and Use	N/A	N/A	N	N/A	Y	N	
8.20	Other Equipment and Facilities	N	N	N	N	Y	N	
8.21	Radiation Protection Program	G	G	G	G	G	G	
8.22	Safety Procedures and Instructions	N/A	N/A	N/A	N/A	Y	N/A	
8.23	Occupational Dose	P	P	P	P	P	P	M
8.24	Area Surveys	P	P	P	P	P	P	R
8.25	Safe Use of Unsealed Licensed Material	P	P	N/A	N/A	N/A	P	T
8.26	Spill/Contamination Procedures	P	P	P	N/A	N/A	P	N

Table C.1 Applicability Table								
Section #	**Topic**	**35.100/200**	**35.300**	**35.400**	**35.500**	**35.600**	**35.1000**	**APP**
8.27	Service of Therapy Devices Containing Sealed Sources	N/A	N/A	N/A	N/A	Y	Y	
8.28	Minimization of Contamination	N	N	N	N	N	N	
8.29	Waste Management	P	P	P	P	P	P	W
8.30	Fees	Y	Y	Y	Y	Y	Y	
8.31	Certification	Y	Y	Y	Y	Y	Y	
8.32	Safety Instruction for Individuals in Restricted Areas	N	N	N	N	N	N	J
8.33	Public Dose	N	N	N	N	N	N	
8.34	Opening Packages	N	N	N	N	N	N	
8.35	Written Directive Procedures	N/A	N	N	N/A	N	N	S
8.36	Release of Patients or Human Research Subjects	N	N	N	N/A	N/A	N	U
8.37	Mobile Medical Service	N	N	N	N	N	N	V
8.38	Audit Program	N	N	N	N	N	N	L
8.39	Operating and Emergency Procedures	N	N	N	N	N	N	N
8.40	Material Receipt and Accountability	N	N	N	N	N	N	
8.41	Ordering and Receiving	N	N	N	N	N	N	O
8.42	Sealed Source Inventory	N	N	N	N	N	N	
8.43	Records of Dosages and Use of Brachytherapy Source	N	N	N	N	N	N	
8.44	Recordkeeping	N	N	N	N	N	N	X
8.45	Reporting	N	N	N	N	N	N	Y
8.46	Leak Tests	N	N	N	N	N	N	Q

Table C.1 Applicability Table								
Section #	**Topic**	**35.100/200**	**35.300**	**35.400**	**35.500**	**35.600**	**35.1000**	**APP**
8.47	Safety Procedures for Treatments when Patients are Hospitalized	N/A	N	N	N/A	N**	N	
8.48	Transportation	N	N	N	N	N	N	Z
* Y beside item 8.13~~4~~4a and 8.14b for use under 35.400 applies to Sr-90 sources for ophthalmic treatment only. ** N/A for teletherapy and gamma stereotactic radiosurgery outpatient treatments.								

Table C.2 outlines the detailed responses that may be made to Items 5 and 6 on Form 313 for the type of radioactive material requested and the purposes for which it will be used. For example, if the applicant is seeking a license for unsealed byproduct material under 10 CFR 35.100 or 35.200, then the applicant should check the "yes" column next to 10 CFR 35.100 and 35.200 in Table C.2. The table then indicates appropriate responses for that type of use. An applicant may copy the checklist and include it in the license application.

The applicant should review the guidance in Section 5.2 and mark security-related information appropriately.

Note: The NRC now has regulatory authority for accelerator-produced radioactive material and discrete sources of Ra-226, as a result of the EPAct. Uses of these materials are added to Table C.2.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

❑ Yes ❑ No	This response includes security-related sensitive information (see Section 5.2) which is included in Attachment _____ and marked "Security-related information – withhold under 10 CFR 2.390"

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Any byproduct material permitted by 10 CFR 35.100	Any	As needed	Any uptake, dilution, and excretion study permitted by 10 CFR 35.100.
	Any byproduct material permitted by 10 CFR 35.200	Any	As needed	Any imaging and localization study permitted by 10 CFR 35.200.
	F-18	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	O-15	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).
	C-11	Any	_____ curies	Production of PET radioactive drugs under 10 CFR 30.32(j).

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

	Any byproduct material permitted by 10 CFR 35.300	Any	______ millicuries	Any radiopharmaceutical therapy procedure permitted by 10 CFR 35.300.
	Iodine-131	Any	___millicuries	Administration of I-131 sodium iodide.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide ________)	Sealed source or device (Manufacturer ___________________, Model No.__________)	___millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide ________)	Sealed source or device (Manufacturer ___________________, Model No.__________)	___millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide ________)	Sealed source or device (Manufacturer __________________, Model No.________)	___millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.400 (Radionuclide ________)	Sealed source or device (Manufacturer __________________, Model No.________)	___millicuries	Any brachytherapy procedure permitted by 10 CFR 35.400.

Table C.2 Items 5 and 6 on NRC Form 313: Radioactive Material and Use

(If using this checklist, check applicable rows and fill in details, and attach copy of checklist to the application.)

Yes	Radionuclide	Form or Manufacturer/ Model No.	Maximum Quantity	Purpose of Use
	Strontium-90	Sealed source or device (Manufacturer _____, Model No._____)	___millicuries	Treatment of superficial eye conditions using an applicator distributed pursuant to 10 CFR 32.74 and permitted by 10 CFR 35.400.
	Byproduct material permitted by 10 CFR 35.500 Check all that apply: ☐ Gd-153; ☐ I-125; ☐Radionuclide (transmission sources bundled and exceeding single source limits in 35.65) ☐ Other, describe	Sealed source or device (Manufacturer _____, Model No._____)	___curies per source and ___curies total	Diagnostic medical use of sealed sources permitted by 10 CFR 35.500 in compatible devices registered pursuant to 10 CFR 30.32(g).

	Iridium-192	Sealed source or device (Manufacturer _____, Model No._____)	___curies per source and ___curies total	One source for medical use permitted by 10 CFR 35.600, in a Manufacturer _____, Model No. _____ remote afterloading brachytherapy device. One source in its shipping container as necessary for replacement of the source in the remote afterloader device.
	Cobalt-60	Sealed source or device (Manufacturer _____, Model No._____)	___curies per source and ___curies total	One source for medical use permitted by 10 CFR 35.600, in a Manufacturer _____, Model No. _____ teletherapy unit. One source in its shipping container as necessary for replacement of the source in the teletherapy unit.
	Cobalt-60	Sealed source or device (Manufacturer _____, Model No._____)	___curies per source and ___curies total	For medical use permitted by 10 CFR 35.600, in a Manufacturer _____, Model No. _____ stereotactic radiosurgery device. Sources in the shipping container as necessary for replacement of the

				sources in the stereotactic radiosurgery device.
	Any byproduct material under 10 CFR 31.11	Prepackaged kits	___millicuries	*In vitro* studies.
	Depleted uranium	Metal	___kilograms	Shielding in a teletherapy unit.
	Depleted uranium	Metal	___kilograms	Shielding in a linear accelerator.
	Any radionuclide in excess of 30 millicuries for use in calibration, transmission, and reference sources. (List radionuclide: _____)	Sealed source or device (Manufacturer _____, Model No._____)	___millicuries	For use in a Manufacturer _____, Model No. _____ for calibration and checking of licensee's survey instruments.
	Americium-241	Sealed source or device (Manufacturer _____, Model No._____)	___millicuries per source and ___millicuries total	Use as an anatomical marker.

	Plutonium (principal radionuclide Pu-238)	Sealed sources	___millicuries per source and ___grams total	As a component of Manufacturer _____, Model No. _____ nuclear-powered cardiac pacemakers for clinical evaluation in accordance with manufacturer's protocol dated _____. This authorization includes: follow-up, explantation, recovery, disposal, and implantation.
	Other	Form or Manufacturer/Model No. _____	___millicuries	Purpose of use _____.

Table C.3 contains a checklist that may be used to identify the attached documents that the applicant is supplying for items for which a response is required. For example, an applicant may fill in the name of the Radiation Safety Officer in Table C.3 and then check the boxes indicating which documents pertaining to the RSO are being included in the license application. An applicant may copy the checklist and include it in the license application.

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal

(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)

Item Number and Title	**Suggested Response**	**Check box to indicate material included in application**
Item 7: [ ] Radiation Safety Officer or [ ] Associate Radiation Safety Officer	*For an individual previously identified as an RSO or ARSO on an NRC or Agreement State license or permit:*	
Name:	Previous license number (if issued by the NRC), or a copy of a license (if issued by an Agreement State), or a copy of a permit (if issued by an NRC master materials licensee) on which the individual was specifically named as the RSO or ARSO. After [**Effective DATE of the Rule**], documentation of the training requirements in § 35.50(d) for any new materials or new medical uses requested.	❐

Table C.3 Items 7 through 11 on NRC Form 313: Training & Experience, Facilities & Equipment, Radiation Protection Program, and Waste Disposal *(Check all applicable rows and fill in details and attach a copy of the checklist to the application or provide information separately.)*		
Item Number and Title	**Suggested Response**	**Check box to indicate material included in application**
	For an individual qualifying under 10 CFR 35.57(a)(3):	
	Documentation that the individual was: - the RSO for only the medical uses of accelerator-produced radioactive material, ~~or~~ discrete sources of Ra-226, or both ~~included in the definition of byproduct material as a result of the EPAct~~; - the RSO for the medical uses of these materials at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or at an earlier date as noticed by the NRC~~during the effective period of NRC's waiver of August 31, 2005~~.	☐ ☐
	For an individual qualifying under 10 CFR 35.50(a):	
	Copy of certification by a specialty board whose certification process has been recognized[1] by NRC or an Agreement State under 10 CFR 35.50(a). **AND**	☐

1[1]The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site http://www.nrc.gov/materials/miau/med-use-toolkit.html.

	Description of the training and experience specified in 10 CFR 35.50(d~~e~~) demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of ~~an~~ the individual ~~to serve~~ as the RSO or ARSO. **AND**	☐
	~~Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed training in and experience required for certification, as well as training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.~~ **~~AND~~**	~~☐~~
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐

For an individual qualifying under 10 CFR 35.50(c)(1):	
Copy of the certification(s) as a medical physicist by a board whose certification process has been recognized[2] by the NRC or an Agreement State under 10 CFR 35.51(a) and description of the experience specified in 10 CFR 35.50(c)(1) demonstrating that the proposed RSO or ARSO is qualified by experience with the radiation safety aspects of similar ~~as applicable to the~~ types of use of byproduct material for which the applicant seeks approval of ~~an~~ the individual ~~to serve~~ as the RSO or ARSO. **AND**	☐
Description of the training and experience specified in 10 CFR 35.50(de) demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of the individual ~~to serve~~ as the RSO or ARSO. **AND**	☐
~~Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the required training and experience specified for certification, as well as training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.~~ **~~AND~~**	☐
If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
For an individual qualifying under 10 CFR 35.57 (a)(2):	
Copy of certification by a specialty board whose certification is listed in 10 CFR 35.57 (a)(2)	☐

2[2]The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site http://www.nrc.gov/materials/miau/med-use-toolkit.html.

Documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005; **AND**	☐
If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59. **AND**	☐
For an individual qualifying under 10 CFR 35.50(c)(2):	
Copy of the Commission or Agreement State license, permit issued by a Commission master material license, permit issued by a Commission or Agreement State licensee of broad scope, or permit issued by a Commission master material license broad scope permittee ~~licensee's license~~ indicating that the individual is an AU, AMP, or ANP identified on the license or permit and has experience with radiation safety aspects of similar types of use of byproduct material for which the applicant seeks approval of ~~an~~ the individual ~~to serve~~ as the RSO or ARSO. **AND**	☐
Description of the training and experience specified in 10 CFR 35.50(de) demonstrating that the proposed RSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of ~~an~~ the individual to serve as RSO or ARSO. **AND**	☐
~~Written attestation, signed by a preceptor RSO, that the individual has satisfactorily completed the requirements in 10 CFR 35.50(c)(2), as well as training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO.~~ **~~AND~~**	☐
If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐

	For an individual applying simultaneously to be the RSO and AU on a new license under 10 CFR 35.50 (c)(3).	
	Documentation of training and experience to be a new AU is attached. **AND**	☐
	The new license application is attached. **AND**	☐
	Description of the training and experience specified in 10 CFR 35.50(d) demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of the individual as the RSO or ARSO.	☐

	For an individual qualifying under 10 CFR 35.50(b):	
	Description of the training and experience specified in 10 CFR 35.50(b) demonstrating that the proposed RSO or ARSO is qualified by training and experience ~~as~~ applicable to the types of use for which the applicant seeks approval of ~~an~~ the individual ~~to serve~~ as the RSO or ARSO. **AND**	☐
	Description of the training and experience specified in 10 CFR 35.50(de) demonstrating that the proposed RSO or ARSO is qualified by training in radiation safety, regulatory issues, and emergency procedures as applicable to the types of use for which the applicant seeks approval of ~~an~~the individual ~~to serve~~ as the RSO or ARSO. **AND**	☐
	Written attestation, signed by a preceptor RSO or ARSO, that the individual has satisfactorily completed the required training and experience specified in 10 CFR 35.50(b)(1), as well as the training in radiation safety, regulatory issues, and emergency procedures for the types of use for which the licensee seeks approval, and is able ~~has achieved a level of radiation safety knowledge sufficient~~ to ~~function~~ independently fulfill the radiation safety-related duties as an RSO or ARSO for a medical use license. **AND**	☐
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐

Item 7: Authorized Users for medical uses: Name(s), (including license number authorizing practice of medicine, podiatry, or dentistry if not provided previously or in attachment); Requested uses for each individual	*For an individual previously identified as an AU on an NRC or Agreement State license or permit:* Previous license number (if issued by the NRC), or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the physician, dentist, or podiatrist was specifically named as an AU for the uses requested.	❒
	For an AU requesting authorization for an additional medical use: Description of the additional training and experience to demonstrate the AU is also qualified for the new medical uses requested (e.g., training and experience needed to meet the requirements in 10 CFR 35.290 (~~b~~c)(1)(ii)(G), 35.396, 35.390(b)(1)(ii)(G), or 35.690(c)). **AND**	❒
	A preceptor attestation, if required (e.g., attestation is required for all individuals to meet the requirements in 10 CFR 35.396 and for individuals seeking authorization under the alternate training and experience pathway for~~,~~ 35.390~~(b)(1)(ii)(G), or~~ and 35.690~~(c)~~).	❒
	For an individual qualifying under 10 CFR 35.57(b)(3):	

	Documentation that the physician, podiatrist, or dentist: • used only accelerator-produced radioactive materials, ~~or~~ discrete sources of Ra-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or at an earlier date as noticed by the NRC~~before or during the effective period of NRC's waiver of August 31, 2005~~; and • used these materials for the same medical uses requested.	☐ ☐
	For an individual who was certified before October 24, 2005, by a board listed in 10 CFR 35.57(b)(2):	
	Copy of the board certification. **AND**	☐
	Documentation demonstrating that the individual was using the requested materials and uses on or before October 24, 2005; **AND**	☐
	If applying for a new medical use, a description of the additional training and experience to demonstrate the individual is also qualified for the new medical uses requested (e.g., training and experience needed to meet the requirements in 10 CFR 35. 290 (c)(1)(ii)(G), 35.396, 35.390(b)(1)(ii)(G), or 35.690(c)). **AND**	☐
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
	For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is board-certified:	

	Copy of the certification(s) by a specialty board(s) whose certification process has been recognized[3] by the NRC under 10 CFR Part 35, Subpart D, E, F, G, or H, as applicable to the use requested. **AND**	☐
	For an individual with a board certification recognized under 10 CFR 35.390, a description of the supervised work experience administering dosages of radioactive drugs required in 10 CFR 35.390(b)(1)(ii)(G) demonstrating that the proposed AU is qualified for the types of administrations for which authorization is sought; **AND**	☐
	For an individual with a board certification recognized under 10 CFR 35.390 for medical uses described in 10 CFR 35.200, a description of the supervised work experience eluting generator systems required in 10 CFR 35.290(c)(1)(ii)(G) demonstrating the proposed AU is also qualified for imaging and localization medical uses; **AND**	☐
	For an individual with a board certification recognized under 10 CFR 35.490 or 35.690 seeking authorization under 10 CFR 35.396(b~~d~~), a description of the classroom and laboratory training and supervised work experience required to demonstrate qualifications for administering parenteral administrations of unsealed byproduct material requiring a written directive; **AND**	☐
	For an individual seeking authorization under 10 CFR Part 35, Subpart H, description of the training specified in 10 CFR 35.690(c) demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought; **AND**	☐

3[3]The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site http://www.nrc.gov/materials/miau/med-use-toolkit.html.

	~~Written attestation, signed by a preceptor physician AU, that the training and experience specified for certification, as well as the clinical casework, or training and experience required by 10 CFR 35.396(d), or training for 10 CFR 35.600 types of use, if appropriate, have been satisfactorily completed and that a level of competency sufficient to function independently as an AU for the medical uses authorized has been achieved;~~ **~~AND~~**	☐
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
	For an individual qualifying under 10 CFR Part 35, Subparts D, E, F, G, and/or H, who is not board-certified:	
	A description of the training and experience identified in 10 CFR Part 35, Subparts D, E, F, G, and H, demonstrating that the proposed AU is qualified by training and experience for the use(s) requested. **AND**	☐
	For an individual seeking authorization under 10 CFR Part 35, Subpart H, description of the training specified in 10 CFR 35.690 (c) demonstrating that the proposed AU is qualified for the type(s) of use for which authorization is sought. **AND**	☐
	Written attestation, signed by a preceptor physician AU, or if applicable the residency program director, that the above training and experience have been satisfactorily completed and the individual is able ~~that a level of competency sufficient~~ to ~~function~~ independently fulfill the radiation safety-related duties as an AU for the requested medical uses ~~authorized has been achieved~~. **AND**	☐
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐

Item 7: Authorized Nuclear Pharmacists	*For an individual previously identified as an ANP on an NRC or Agreement State license or permit:*	
Name(s) and license to practice pharmacy:	Previous license number (if issued by the NRC), or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named ANP.	☐
	For an individual qualifying under 10 CFR 35.57(a)(~~4~~3):	
	Documentation that the nuclear pharmacist: • used only accelerator-produced radioactive materials or discrete sources of Ra-226, or both, in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or at an earlier date as noticed by the NRC~~before or during the effective period of NRC's waiver of August 31, 2005~~; and • used these materials for the same uses requested.	☐ ☐
	For an individual qualifying under 10 CFR 35.55(a):	
	Copy of the certification(s) of the specialty board whose certification process has been recognized[4] under 10 CFR 35.55(a). **AND**	☐
	~~Written attestation, signed by a preceptor ANP, that training and experience required for certification have been satisfactorily completed and that a level of competency sufficient to function independently as an ANP has been achieved.~~ **~~AND~~**	☐

4[4]The names of board certifications that have been recognized by the NRC or an Agreement State are posted on the NRC's Web site http://www.nrc.gov/materials/miau/med-use-toolkit.html.

	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
	For an individual qualifying under 10 CFR 35.55(b):	☐
	Description of the training and experience specified in 10 CFR 35.55(b) demonstrating that the proposed ANP is qualified by training and experience. **AND**	
	Written attestation, signed by a preceptor ANP, that the above training and experience have been satisfactorily completed and the individual is able ~~that a level of competency sufficient~~ to ~~function~~ independently fulfill the radiation safety-related duties as an ANP ~~has been achieved~~. **AND**	☐
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
Item 7: Authorized Medical Physicists Name(s):	*For an individual previously identified as an AMP on an NRC or Agreement State license or permit:*	☐
	Previous license number (if issued by the NRC), or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named an AMP for the uses requested.	

	For an individual qualifying under 10 CFR 35.57(a)(~~4~~3):	
	Documentation that the medical physicist: - used only accelerator-produced radioactive material, discrete sources of Ra-226, or both, for medical uses at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC~~before or during the effective period of NRC's waiver of August 31, 2005~~; and - used these materials for the same medical uses requested.	☐ ☐
	For an individual qualifying under 10 CFR 35.51(a):	
	Copy of the certification(s) of the specialty board(s) whose certification process has been recognized[5] under 10 CFR 35.51(a). **AND**	☐
	Description of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which the applicant seeks approval of an individual as the AMP, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system. **AND**	☐
	~~Written attestation, signed by a preceptor physician AMP, that the training and experience specified for certification, as well as the training and experience specified in 10 CFR 35.51(c) have been satisfactorily completed and that a level of competency sufficient to function independently as an AMP has been achieved;~~ ~~**AND**~~	☐
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐

	For an individual qualifying under 10 CFR 35.57(a)(3):	
	Copy of the certification issued on or before October 24, 2005, by a specialty board listed in 10 CFR 35.57(a)(3). AND	☐
	Documentation that the medical physicist used these materials on or before October 24, 2005, for the same medical uses requested. AND	☐
	If applying for a new medical use, a description of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which the applicant seeks approval of an individual as the AMP, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system. **AND**	☐
	Description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
	For an individual qualifying under 10 CFR 35.51(b):	
	Description of the training and experience demonstrating that the proposed AMP is qualified by training and experience identified in 10 CFR 35.51(b)(1) for the uses requested. **AND**	☐
	Description of the training and experience specified in 10 CFR 35.51(c) demonstrating that the proposed AMP is qualified by training in the types of use for which the applicant seeks approval of an individual as the AMP, including hands-on device operation, safety procedures, clinical use, and operation of a treatment planning system. **AND**	☐

Writt	Written attestation, signed by a preceptor AMP, that the required training and experience have been satisfactorily completed and that the individual is able ~~a level of competency sufficient~~ to ~~function~~independently fulfill the radiation safety-related duties as an AMP ~~has been achieved~~for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. **AND**	☐
	If applicable, description of recent related continuing education and experience as required by 10 CFR 35.59.	☐
Item 7: Ophthalmic physicist Name(s):	Documentation of a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university. AND Documentation of successful completion of 1 year of full-time training in medical physics and an additional year of full-time work experience under a medical physics. AND Documentation of training in: - The creating, modifying, and completing of written directives; - Procedures for administrations requiring a written directive; and - Performing the calibration measurements of brachytherapy sources as detailed in 10 CFR 35.432.	☐ ☐ ☐ ☐
Item 7: Authorized User for nonmedical uses	***Note:*** For purposes of this section of the table, the term "authorized user" is used to mean individuals authorized for the nonmedical uses described. See Sections 8.11 and 8.12.	
	For an individual previously authorized for nonmedical use on an NRC or Agreement State license or permit:	

Name(s): Requested types, quantities, and nonmedical uses for each individual	Previous license number (if issued by the NRC), or a copy of the license (if issued by an Agreement State), or a copy of a permit issued by an NRC master materials licensee, or a copy of a permit issued by an NRC or Agreement State broad-scope licensee, or a copy of a permit issued by an NRC Master Materials License broad-scope permittee on which the individual was specifically named an AU for the types, quantities, and uses requested.	☐
	For individuals qualifying under 10 CFR 30.33(a)(3):	
	Documentation of the individual's training and experience demonstrating that the individual is qualified to use the types and quantities of licensed materials for the requested uses.	☐
Item 9: Facility Diagram	A diagram is enclosed that describes the facilities and identifies activities conducted in all contiguous areas surrounding the area(s) of use. The following information is included:	☐
	• Guidance in Section 5.2 was reviewed and security-related sensitive information provided is marked accordingly.	☐
	• Drawings should be to scale, indicating the scale used.	☐
	• Location, room numbers, and principal use of each room or area where byproduct material is prepared, used or stored, location of direct transfer delivery tubes from a PET radionuclide/radioactive drug production facility or production area of PET radioactive drugs under 10 CFR 30.32(j), and areas where higher energy gamma- emitting radionuclides (e.g., PET radionuclides) are used;	☐
	• Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below therapy treatment rooms, indicating whether the room is a restricted or unrestricted area as defined in 10 CFR 20.1003; and	☐

	• Provide shielding calculations and include information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, including a description of any portable shields used (e.g., shielding of proposed patient rooms used for implant therapy, including the dimensions of any portable shield, if one is used; source storage safe). In addition to the above, for teletherapy and GSR facilities, applicants should provide the directions of primary beam usage for teletherapy units and, in the case of an isocentric unit, the plane of beam rotation.	☐ ☐
Item 9: Radiation Monitoring Instruments	A statement that: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations." **AND/OR**	☐
	A statement that: "We have developed and will implement and maintain written survey meter calibration procedures in accordance with the requirements in 10 CFR 20.1501 and that meet the requirements of 10 CFR 35.61." **AND**	☐
	A description of the instrumentation (e.g., gamma counter, solid state detector, portable or stationary count rate meter, portable or stationary dose rate or exposure rate meter, single or multichannel analyzer, liquid scintillation counter, proportional counter) that will be used to perform required surveys. **AND**	☐
	A statement that: "We reserve the right to upgrade our survey instruments as necessary as long as they are adequate to measure the type and level of radiation for which they are used."	☐

Item 9: Dose Calibrator and Other Dosage Measuring Equipment	A statement that: "Equipment used to measure dosages will be calibrated in accordance with nationally recognized standards or the manufacturer's instructions."	☐
	When administering dosages of alpha-emitting unsealed byproduct material in other than unit dosages made by a manufacturer or preparer licensed under 10 CFR 32.72 or 10 CFR 30.32(j), • A statement that: "Dosages will be determined by relying on the provider's dose label for measurement of the radioactivity and a combination of volumetric measurement and mathematical calculation." **OR**	☐
	• We are providing a description of the dosage measurement equipment, the nationally recognized calibration standard (or manufacturer's calibration instructions), and dosage measurement procedures.	☐
Item 9: Therapy Unit - Calibration and Use	We are providing the procedures required by 10 CFR 35.642, 10 CFR 35.643, and 10 CFR 35.645, if applicable to the license application.	☐
	We are providing the calibration and use procedures requested by NRC licensing guidance on NRC's web site for the following 10 CFR 35.1000 medical uses: _____.	☐
Item 9: Other Equipment and Facilities	Guidance in Section 5.2 was reviewed and security-related information provided is marked accordingly.	☐

	Attached is a description, identified as Attachment 9.4, of additional facilities and equipment.	☐
	For manual brachytherapy facilities, we are providing a description of the emergency response equipment.	☐
	For PET radionuclide use, PET radioactive drug production, and radiopharmaceutical therapy programs, we are providing a description of the additional facilities and equipment for these uses.	☐
	For teletherapy, GSR, and remote afterloader facilities, we are providing a description of the following: • Warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems) for each therapy treatment room; • Area radiation monitoring equipment; • Viewing and intercom systems (except for LDR units); • Steps that will be taken to ensure that no two units can be operated simultaneously, if other radiation-producing equipment (e.g., linear accelerator, X-ray machine) is in the treatment room; • Methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and • Emergency response equipment.	☐ ☐ ☐ ☐ ☐ ☐
	For the following 35.1000 medical uses, we reviewed NRC's licensing guidance on NRC's web site and are providing a description of the equipment and facilities appropriate for each 35.1000 medical use, or explaining why the description is not needed. _____	☐

Item 10: Safety Procedures and Instructions	Attached are procedures required by 10 CFR 35.610.	☐
	For the following 35.1000 medical uses, we reviewed the licensing guidance on NRC's web site and are applying for approval to revise, without further NRC approval, the radiation safety program for each 35.1000 medical use to conform to revised licensing guidance posted on NRC's web site (http://www.nrc.gov/materials/miau/med-use-toolkit.html). _____	☐
	For the following 35.1000 medical uses, we reviewed NRC's licensing guidance on NRC's web site and are providing safety and emergency procedures appropriate for each 35.1000 medical use, or explaining why the description is not needed. _____	☐
	Guidance in Section 5.2 was reviewed and security-related sensitive information provided is marked accordingly.	☐
Item 10: Occupational Dose	A statement that: "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG-1556, Vol. 9, Rev. 1, 'Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses.' " **OR**	☐
	A description of an alternative method for demonstrating compliance with the referenced regulations.	☐
Item 10: Area Surveys	A statement that: "We have developed and will implement and maintain written procedures for area surveys in accordance with 10 CFR 20.1101 that meet the requirements of 10 CFR 20.1501 and 10 CFR 35.70."	☐

Item 10: Safe Use of Unsealed Licensed Material	A statement that: "We have developed and will implement and maintain procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1301."	❑
Item 10: Spill/Contamina-tion Procedures	A statement that: "We have developed and will implement and maintain written procedures for safe response to spills of licensed material in accordance with 10 CFR 20.1101."	❑
Item 10: Installation, Maintenance, Adjustment, Repair, and Inspection of Therapy Devices Containing Sealed Sources	Name of the proposed employee and types of activities requested: _____ **AND**	❑
	Description of the training and experience demonstrating that the proposed employee is qualified by training and experience for the use requested. **AND**	❑
	Copy of the manufacturer's training certification and an outline of the training in procedures to be followed.	❑
Item 10: Minimization of Contamination	A response is not required under the following condition: the NRC will consider that the above criteria have been met if the information provided in applicant's responses satisfy the criteria in Sections 8.15, 8.16, 8.21, 8.25, 8.27, and 8.29, on the topics: facilities and equipment, facility diagram, Radiation Protection Program, safety program, and waste management.	N/A
Item 11: Waste Management	A statement that: "We have developed and will implement and maintain written waste disposal procedures for licensed material in accordance with 10 CFR 20.1101, that also meet the requirements of the applicable section of 10 CFR Part 20, Subpart K, and of 10 CFR 35.92."	❑
	Attached is a description of the radioactive waste incinerator facility and related portions of the Radiation Safety Program (10 CFR 20.2004).	❑

	Attached is a request to receive potentially contaminated radiation transport shields from consortium members receiving PET radioactive drugs noncommercially transferred under 10 CFR 30.32(j) authorization.	❑

APPENDIX D

Documentation of Training and Experience to Identify Individuals on a License as Authorized User, Radiation Safety Officer, Associate Radiation Safety Officer, Authorized Medical Physicist, Ophthalmic Physicist, or Authorized Nuclear Pharmacist

Note: The most current guidance is found on NRC's public Web site at http://www.nrc.gov/materials/miau/med-use-toolkit.html (Medical Uses Toolkit).

Documentation of Training and Experience to Identify Individuals on a License as Authorized User, Radiation Safety Officer, Associate Radiation Safety Officer, Authorized Medical Physicist, Ophthalmic Physicist, or Authorized Nuclear Pharmacist

I. Experienced Authorized Users, Authorized Medical Physicists, Ophthalmic Physicists, Authorized Nuclear Pharmacists, Radiation Safety Officer, or Associate Radiation Safety Officers

An applicant or licensee who is adding an experienced authorized user (AU) for medical uses, authorized medical physicist (AMP), ophthalmic physicist, authorized nuclear pharmacist (ANP), Radiation Safety Officer (RSO) or Associate Radiation Safety Officer (ARSO) to its medical use license or application only needs to provide evidence that the individual is listed on a medical use license issued by the NRC or Agreement State, a permit issued by an NRC master materials licensee, a permit issued by an NRC or Agreement State broad-scope licensee, or a permit issued by an NRC master material broad-scope permittee, provided that the individual is authorized for the same types of use(s) requested in the application under review, and the individual meets the recentness of training criteria described in 10 CFR 35.59. When adding an experienced ANP to the license, the applicant also may provide evidence that the individual is listed on an NRC or Agreement State commercial nuclear pharmacy license or identified as an ANP by a commercial nuclear pharmacy authorized to identify ANPs. For individuals who have been previously authorized by, but not listed on, the commercial nuclear pharmacy license, medical broad-scope license, or Master Materials License medical broad-scope permit, the applicant should submit either verification of previous authorizations granted or evidence of acceptable training and experience.

II. Experienced Physicians, Podiatrists, Dentists, Nuclear Pharmacists, Medical Physicists, and Radiation Safety Officers Who Only Used Accelerator-Produced Nuclear Materials, or Discrete Sources of Radium-226, or Both, for Medical or Nuclear Pharmacy Uses.

In implementing the EPAct, the NRC “grandfathered” physicians, podiatrists, dentists, medical physicists, and nuclear pharmacists that used only accelerator-produced radioactive materials, discrete sources of radium-226 (Ra-226), or both, for medical or nuclear pharmacy uses at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC~~before or under the NRC waiver of August 31, 2005~~, when using these materials for the same uses. These individuals, as well as individuals that performed RSO duties only for uses of accelerator-produced radionuclides or discrete sources of Ra-226 at medical or nuclear pharmacy facilities before or during the effective period of the waiver, do not have to meet the requirements of 10 CFR 35.59, or the training and experience requirements in 10 CFR Part 35, Subparts B, D, E, F, and G.

The applicant or licensee that is adding one of these experienced individuals to its medical use license should document that the individual used only accelerator-produced radionuclides, or discrete sources of Ra-226, or both, for medical or nuclear pharmacy uses before or during the effective period of the waiver and that the materials were used for the same uses requested. This documentation may be, but is not restricted to, evidence that the individual was listed on an Agreement State or non-Agreement State license or permit authorizing these materials for the requested uses.

III. Applications that Include New Authorized User, Authorized Medical Physicist, Ophthalmic Physicist, Authorized Nuclear Pharmacist, ~~or~~ Radiation Safety Officer or Associate Radiation Safety Officer Recognition by NRC

Applicants should submit the appropriate completed form in the NRC Form 313A series to show that the individuals meet the correct training and experience criteria in 10 CFR Part 35, Subparts B, D, E, F, G, and H. For the applicant's convenience, the NRC Form 313A series has been separated into six separate forms. The forms are NRC FORM 313A (RSO) for the Radiation Safety Officer and Associate Radiation Safety Officer ; NRC FORM 313A (AMP) for the authorized medical physicist and ophthalmic physicist; NRC FORM 313A (ANP) for the authorized nuclear pharmacist; NRC FORM 313A (AUD) for the authorized user of the medical uses included in 10 CFR 35.100, 35.200, ~~and/~~or 35.500; NRC FORM 313A (AUT) for the authorized user for the medical use included in 10 CFR 35.300; and NRC FORM 313A (AUS) for the authorized user for the medical uses included in 10 CFR 35.400 and/or 35.600.

When an applicant wants to identify one or more ARSOs, it must describe the portions of the licensed program for which the ARSO will be assigned duties and task in the oversight of the radiation safety operations, so that the NRC is assured that the individual has the requisite training and experience needed to meet the requirements in 10 CFR 35.50(d).

There are two primary training and experience routes to qualify an individual as a new AU, AMP, ANP, RSO or ARSO. The first is by means of certification by a board recognized by NRC and listed on the NRC Web site as provided in 10 CFR 35.50(a), 35.51(a), 35.55(a), 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a), or included in the regulations in 35.57(a)(2), 35.57(a)(3), 35.57(b)(2). ~~Preceptor attestations must also be submitted for all individuals to qualify under 10 CFR Part 35, Subparts B and D through H.~~ Additional training may also need to be documented for RSOs, ARSOs, AMPs, and AUs under 10 CFR 35.50, 35.51, 35.300 and 35.600.

The second route is by meeting the structured educational program, supervised work experience, and preceptor attestation requirements in 10 CFR Part 35, Subparts B, D, E, F, G, and H. In some cases there may be additional training and experience routes and requirements for recognized AUs, ANPs, AMPs, RSOs or ARSOs to seek additional authorizations.

IV. Recentness of Training

The required training and experience, including board certification, described in 10 CFR Part 35 must be obtained within the 7 years preceding the date of the application, or the individual must

document having had related continuing education, retraining, and experience since obtaining the required training and experience. Examples of acceptable continuing education and experience for physicians include the following:

- Successful completion of classroom and laboratory review courses that include radiation safety practices relative to the proposed type of authorized medical use,
- Practical and laboratory experience with patient procedures using radioactive material for the same use(s) for which the applicant is requesting authorization,
- Practical and laboratory experience under the supervision of an AU at the same or another licensed facility that is authorized for the same use(s) for which the applicant is requesting authorization, and

  For therapy devices, experience with the therapy unit and/or comparable linear accelerator experience and completion of an in-service review of operating and emergency procedures relative to the therapy unit to be used by the applicant.

V. General Instructions and Guidance for Filling Out NRC Form 313A Series

If the applicant is proposing an individual for more than one type of authorization, the applicant may need to either submit multiple forms in the NRC Form 313A series or fill out some sections more than once. For example, an applicant that requests a physician be authorized for 10 CFR 35.200 and 10 CFR 35.300 medical uses and as the RSO, should provide three completed NRC Form 313A series forms (i.e., NRC Form 313A (RSO), NRC Form 313A (AUD) and NRC Form 313A (AUT)). Also, if the applicant requests that a physician be authorized for both high dose-rate remote afterloading and gamma stereotactic radiosurgery under 10 CFR 35.600, only one form, NRC Form 313A (AUS) needs to be completed, but one part (i.e., "Supervised Work and Clinical Experience") must be filled out twice.

To identify an Agreement State license, provide a copy of the license. To identify a Master Materials License permit, provide a copy of the permit. To identify an individual (i.e., supervising individual or preceptor) who is authorized under a broad-scope license or broad-scope permit of a Master Materials License, provide a copy of the permit issued by the broad-scope licensee/permittee. Alternatively, provide a statement signed by the Radiation Safety Officer or chairperson of the Radiation Safety Committee similar to the following: "_____(name of supervising individual or preceptor) is authorized under _____(name of licensee/permittee) broad-scope license number_____ to use_____(materials) during _____(time frame)."

INTRODUCTORY INFORMATION

Name of individual

Provide the individual's complete name so that NRC can distinguish the training and experience received from that received by others with a similar name.

Note: Do not include personal or private information (e.g., date of birth, Social Security Number, home address, personal telephone number) as part of your qualification documentation.

State or territory where licensed

The NRC requires physicians, dentists, podiatrists, and pharmacists to be licensed by a State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine, as well as licensed in the practice of dentistry, podiatry, or pharmacy, respectively (see definitions of “physician”, “dentist”, “podiatrist”, and “pharmacist” in 10 CFR 35.2).

Requested Authorization(s).

Check all authorizations that apply and fill in the blanks as provided.

Part I. Training and Experience

There are always multiple pathways provided for each training and experience section. Select the applicable one.

Item 1. Board Certification

The applicant or licensee may use this pathway if the proposed new authorized individual is certified by a board recognized by NRC (to confirm that NRC recognizes that board’s certifications, see NRC's Web site http://www.nrc.gov/materials/miau/med-use-toolkit.html or if certified prior to October 24, 2005, by a board listed in 10 CFR 35.57.

Note: An individual that is board-eligible will not be considered for this pathway until the individual is actually board-certified. Further, individuals holding other board certifications will also not be considered for this pathway.

The applicant or licensee will need to provide a copy of the board certification and other documentation of training, experience, or clinical casework as indicated on the specific form of the NRC Form 313A series.

With the exception of an applicant requesting a proposed individual under the provisions of 10 CFR 35.396, board certified applicants do not need to provide a preceptor attestation.

~~All applicants under this pathway (except for 10 CFR 35.500 uses) must submit a completed Part II Preceptor Attestation.~~

Item 2. Current Authorized Individuals Seeking Additional Authorizations

Provide the information requested for training, experience, or clinical casework as indicated on the specific form of the NRC Form 313A series. (***Note:*** This section does not include individuals who are authorized only on foreign licenses.)

With the exception of applicants seeking authorizations for individuals applying under 10 CFR 35.396, board certified applicants do not need to provide a preceptor attestation. All ~~other~~ non-board certified individuals seeking ~~applicants for~~ additional authorizations (except those applying for 35.500 medical uses) ~~under this pathway~~, the applicant must submit a completed Part II Preceptor Attestation.

Item 3. Alternate Pathway for Training and Experience for Proposed New Authorized Individuals

This pathway is used for those individuals not listed on the license as authorized individuals, who do not meet the requirements for the board certification pathway.

The regulatory requirements refer to two categories of training: (a) classroom and laboratory training, and (b) supervised work experience. All hours credited to classroom and laboratory training must relate directly to radiation safety and safe handling of byproduct material and be allocated to one of the topics in the regulations. Each hour of training involving performance of radiation safety tasks or hands-on use of byproduct material may be credited to either (a) classroom and laboratory training, or (b) supervised work experience. Note that a single hour of training may only be counted once and may not be credited to both of these categories.

The proposed authorized individual may receive the required classroom and laboratory training, supervised work experience, and clinical casework at a single training facility or at multiple training facilities; therefore, space is provided to identify each location and date of training or experience. The date should be provided in the month/day/year (mm/dd/yyyy) format.

The specific number of hours needed for each training and supervised work experience element will depend upon the type of approval sought. Under the “classroom and laboratory training,” provide the number of clock hours spent on each of the topics listed in the regulatory requirements.

The proposed authorized individual may obtain the required “classroom and laboratory training” in any number of settings, locations, and educational situations. For example, at some medical teaching/university institutions, a course may be provided for that particular need and taught in consecutive days. In other training programs, the period may be a semester or quarter as part of the formal curriculum. Also, the classroom and laboratory training may be obtained using a variety of other instructional methods. Therefore, the NRC will broadly interpret “classroom and laboratory training” to include various types of instruction, including online training, as long as it meets the specific clock hour requirements and the subject matter relates to radiation safety and safe handling of byproduct material for the uses requested.

Under the “supervised work experience” sections of the forms, provide only the total number of hours of supervised work experience and check the boxes for each of the topics listed in the regulatory requirements to confirm that the listed subject areas were included in the supervised work experience.

The “supervised work experience” for physicians must include, but is not limited to, the subject areas listed in the applicable training and experience requirements. The NRC recognizes that

physicians in training will not dedicate all of their supervised work experience time specifically to the subject areas listed in the regulatory requirements and will be attending to other clinical activities involving the medical use of byproduct material (e.g., reviewing case histories or interpreting scans). Hours spent on these other duties not directly related to radiation safety or hands-on use of byproduct material, even though not specifically required by the NRC, may be credited to the supervised work experience category but not to the classroom and laboratory training category.

For nuclear pharmacists, under the "supervised practical experience" section, provide the number of clock hours for each topic. The supervised practical experience topics for the nuclear pharmacists include all the basic elements in the practice of nuclear pharmacy. Therefore, all the hours of supervised experience are allocated to these topics.

The applicant must submit a completed Part II Preceptor Attestation for all non-board certified individuals (except for ophthalmic physicist and individuals meeting just the criteria for 35.500 medical uses)

Note: If the proposed new authorized individual had more than one supervisor, provide the information requested for each supervising individual.

Part II. Preceptor Attestation

The NRC defines the term "preceptor" in 10 CFR 35.2, "Definitions," to mean "an individual who provides, directs, or verifies training and experience required for an individual to become an AU, an AMP, an ANP, an ARSO, or an RSO." While the supervising individual for the work experience may also be the preceptor, the preceptor does not have to be the supervising individual as long as the preceptor directs or verifies the training and experience required. The preceptor must attest in writing regarding the training and experience of any individual to serve as an authorized individual and attest that the individual has satisfactorily completed the appropriate training and experience requirements and is able ~~has achieved a level of competency or a level of radiation safety knowledge sufficient~~ to ~~function~~ independently fulfill the radiation safety-related duties of an authorized individual. The preceptor language in NRC Forms 313A (AUD), 313A (AUT), and 313A (AUS) does not require an attestation of general clinical competency but requires sufficient attestation to demonstrate that the individual is able ~~has the knowledge~~ to fulfill the duties of the position for which the attestation is sought. The preceptor also has to meet specific requirements.

The NRC may require supervised work experience conducted under the supervision of an authorized individual in a licensed material use program. In this case, a supervisor is an individual who provides frequent direction, instruction, and direct oversight of the student as the student completes the required work experience in the use of byproduct material.

Supervision may occur at various licensed facilities, from a large teaching university hospital to a small private practice.

The NRC Form 313A series Part II - Preceptor Attestation has multiple sections. The preceptor must complete an attestation of the proposed user's training, experience, and that the proposed user is able ~~competency~~ to ~~function~~ independently fulfill the radiation safety-related duties for the authorization sought, as well as provide information concerning his/her own qualifications and sign the attestation. Because there are a number of different pathways to obtain the required training and experience for different authorized individuals, specific instructions are provided below for each form in the NRC 313A series.

VI. RADIATION SAFETY OFFICER and ASSOCIATE RADIATION SAFETY OFFICER - Specific Instructions and Guidance for Filling Out NRC Form 313A (RSO)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

When requesting approval for an RSO or ARSO, to ensure that the requirements of section 30.33 are met, the applicant must designate whether the individual will be an RSO or ARSO. The applicant must also specify the medical uses for which the RSO will have responsibilities and the portion of the program for which the ARSO will have duties and task in the oversight of the radiation safety operations. The RSO has responsibility for the entire radiation safety program. The RSO responsibilities are identified by all the specific medical uses (e.g., 35.100, 35.200) that will be listed on the license. The oversight duties and task for the ARSO also include "other". "Other" may be used to designate program divisions such as different geographic locations or health physics functions.

Part I. Training and Experience - select one of four methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification, and documentation of specific radiation safety training for all types of use on the license~~, and a completed preceptor attestation~~). As indicated on the form, additional information is needed if the board certification or radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, ARSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 5~~3~~.c if the training was provided by an RSO, ARSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 2. Current Radiation Safety Officer Seeking Authorization to Be Recognized as a Radiation Safety Officer for the Additional Medical Use(s) Checked Above.

Provide the requested information (i.e., documentation of specific radiation safety training (complete the table in 5~~3~~.c) and a completed preceptor attestation in Part II if the individual is not board certified). As indicated on the form, additional information is needed if the specific radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, ARSO, AMP, ANP, or AU who is authorized for that type of use. Specific information regarding the supervising individual only needs to be provided in the table in 5.c if the training was provided by an RSO, ARSO, AMP, ANP, or AU. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 3. Authorized User, Authorized Medical Physicist, or Authorized Nuclear Pharmacist Identified on a License or Permit as Specified in 10 CFR 35.50(c)(2) ~~the licensee's license~~

Provide the requested information (i.e., the license number and documentation of specific radiation safety training for each use on the license (complete the table in 5~~3~~.c)). As indicated on the form, additional information is needed if the specific radiation safety training was completed more than 7 years ago.

Specific radiation safety training for each type of use on the license may be supervised by an RSO, ARSO, AMP, ANP, or AU who is authorized for that type of use. ~~Specific information regarding the supervising individual only needs to be provided in the table in table 3.c if the training was provided by an RSO, AMP, ANP, or AU.~~ If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 4. Individuals Applying to be Simultaneously the RSO and AU on a New License

When the application is for a new medical use license and the proposed AU has never been recognized as an AU, the individual will be qualified to be the RSO on the new license based upon his or her experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as RSO and AU. Therefore, the applicant must submit documentation of training and experience for the individual to be an AU (NRC Form 313A (AUD), 313A (AUT), or 313A (AUS)) with the NRC Form 313A (RSO) as well as complete table 5.c. This documents the individual has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. If there was more than one supervising individual, identify each supervising individual by name and provide his/her qualifications.

Item 5. Structured Educational Program for Proposed New Radiation Safety Officer or Associate Radiation Safety Officer

As indicated on the form, additional information is needed if the training, supervised radiation safety experience and specific radiation safety training was completed more than 7 years ago.

Submit a completed Section 5~~3~~.a.

Submit a completed Section 5~~3~~.b. The individual must have completed 1 year of full-time radiation safety experience under the supervision of an RSO or ARSO. This is documented in Section 5.b by providing the ranges of dates for supervised radiation safety experience. If there was more than one supervising individual, identify each supervising individual by name and provide his/her qualifications.

Provide the requested information (i.e., documentation of specific radiation safety training for each use on the license (complete the table in 5~~3~~.c)). Specific radiation safety training for each type of use on the license may be supervised by an RSO, ARSO, AMP, ANP, or AU who is authorized for that type of use. ~~Specific information regarding the supervising individual only needs to be provided in the table in table 3.c if the training was provided by an RSO, AMP, ANP, or AU.~~ If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Preceptor Attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation page has four sections.

The attestation for the new proposed RSO's or ARSO's training ~~or identification on the license as an AU, AMP, or ANP~~ is in the first section.

The attestation for the specific radiation safety training is in the second section.

The attestation ~~for~~ that the individual~~'s~~ is able ~~competency~~ to ~~function~~ independently fulfill the radiation safety-related duties as an RSO (or as an ARSO)~~, and~~ for a medical use license is in the third section.

The fourth and final section requests specific information about the preceptor's authorization as an RSO or ARSO on a medical use license in addition to the preceptor's signature.

The preceptor for a new proposed RSO or ARSO must fill out all four sections.

The preceptor for an RSO or ARSO, who did not become authorized via the board certification pathway, who is seeking authorization to be recognized as an RSO or ARSO for the additional medical use(s) must fill out the second, third, and fourth sections.

VII. AUTHORIZED MEDICAL PHYSICIST AND OPHTHALMIC PHYSICIST- Specific Instructions and Guidance for Filling Out NRC Form 313A (AMP)

See Section V, “General Instructions and Guidance for Filling Out NRC Form 313A Series,” for additional clarification on providing information about an individual’s status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

When requesting approval for an AMP or ophthalmic physicist, the applicant must designate whether the individual will be an AMP or an ophthalmic physicist.

Part I. Training and Experience - select one of the three methods below:

Authorized Medical Physicist

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification and documentation of device-specific training in the table in 3.c~~, and a completed Preceptor Attestation~~). As indicated on the form, additional information is needed if the board certification or device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

If the individuals board certification was issued on or before October 24, 2005, and is listed in 10 CFR 35.57(a)(3), attach documentation that the individual performed the requested type of use on or before October 24, 2005. Also provide the dates, duration, and description of continuing education and experience for each requested type of use within the past 7 years.

Item 2. Current Authorized Medical Physicist Seeking Additional Uses(s) Checked above

Provide the requested information (i.e., documentation of device-specific training (complete the table in 3.c) and, for an individual who did not become authorized via the board certification pathway who is seeking a new authorization, complete the Preceptor Attestation in Part II). As indicated on the form, additional information is needed if the device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising medical physicist provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 3. Training and Experience for Proposed Authorized Medical Physicist

As indicated on the form, additional information is needed if the degree, training, and/or work experience was completed more than 7 years ago.

Submit a completed Section 3.a. Submit documentation of a graduate degree (for example, a copy of a diploma or transcript from an accredited college or university).

Submit a completed Section 3.b. The individual must have completed 1 year of full-time training in medical physics and an additional year of full-time work experience, which cannot be concurrent. This is documented in Section 3.b by providing the ranges of dates for training and work experience.

If the proposed AMP had more than one supervisor, provide the information requested in Section 3.b for each supervising individual. If the supervising individual is not an AMP, the applicant must provide documentation that the supervising individual meets the requirements in 10 CFR 35.51 and 10 CFR 35.59.

Submit a completed Section 3.c for each specific device for which the applicant is requesting authorization.

Device-specific training may be provided by the vendor or a supervising medical physicist authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.c if the training was provided by an AMP. If more than one supervising medical physicist provided the training, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Preceptor Attestation in Part II.

Item 4. Training and Experience for Proposed Ophthalmic Physicist

Submit a completed Section a. Submit documentation of a graduate degree (for example, a copy of a diploma or transcript from an accredited college or university).

Submit a completed Section b. The proposed ophthalmic physicist must have completed 1 year of full time training in medical physics and an additional year of full time work experience in medical physics. Provide the name of the facility where the training and the facility where the work experience took place and the name of the supervising medical physicist.

Submit a completed Section c. Document completion of specific training in each area specified in the table. If more than one supervising individual provided the training, identify each

supervising individual by name and identify license or permit number where they used byproduct material.

Note: A preceptor attestation is not required for this individual.

Part II. Preceptor Attestation

The Preceptor Attestation page has four sections.

The attestation to the proposed AMP's training is in the first section.

The attestation for the device-specific training is in the second section.

The attestation of the individual's ability ~~competency~~ to ~~function~~ independently fulfill the radiation safety-related duties as an AMP for the specific devices requested by the applicant is in the third section.

The fourth and final section requests specific information about the preceptor's authorizations to use licensed material, in addition to the preceptor's signature.

The preceptor for a proposed new AMP must fill out all four sections of this page. The preceptor for an AMP, who did not become authorized via the board certification pathway and is seeking additional authorizations, must complete the last three sections.

VIII. AUTHORIZED NUCLEAR PHARMACIST - Specific Instructions and Guidance for Filling Out NRC Form 313A (ANP)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the two methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification ~~and a completed Preceptor Attestation~~). As indicated on the form, additional information is needed if the board certification occurred more than 7 years ago.

Item 2. Structured Educational Program for a Proposed Authorized Nuclear Pharmacist

As indicated on the form, additional information is needed if the training and/or supervised practical experience was completed more than 7 years ago.

Submit completed Sections 2.a and 2.b. If the proposed new nuclear pharmacist had more than one supervisor, provide the name of each supervising individual in Section 2.b.

Submit a completed Preceptor Attestation.

Part II. Preceptor Attestation

The Preceptor Attestation ~~page~~ has two sections. The preceptor must ~~select either the board certification or the structured educational program when filling out the~~ provide his or her attestation in the first section on this page.

The second and final section of the page requests specific information about the preceptor's authorization to use licensed material, in addition to the preceptor's signature.

IX. 10 CFR 35.100, 35.200, AND 35.500 AUTHORIZED USERS - Specific Instructions and Guidance for Filling Out NRC Form 313A (AUD)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the three methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification ~~and a completed Preceptor Attestation~~). As indicated on the form, additional information is needed if the board certification occurred more than 7 years ago.

Item 2. Current 35.390 Authorized User Seeking Additional 10 CFR 35.290(c)(1)(ii)(G) Authorization

(a) Fill in the blank in Section 2.a with the current license number on which the proposed user is listed.

(b) Provide a description of the proposed user's experience that meets the requirements of 10 CFR 35.290 (c)(1)(ii)(G) as shown in the table in 2.b. As indicated on the form, additional information is needed if this experience was obtained more than 7 years ago.

List each supervising individual by name and include the license showing the supervising individual as an AU or an ANP if the supervising individual for the 35.290(c)(1)(ii)(G) supervised work experience is an ANP.

Item 3. Training and Experience for Proposed Authorized Users

As indicated on the form, additional information is needed if the training and/or work experience was completed more than 7 years ago.

Note: Providing the training and experience information required under 10 CFR 35.290 will allow the individual to be authorized to use materials permitted by both 10 CFR 35.100 and 10 CFR 35.200.

Submit a completed Section 3.a for each proposed authorized use.

Submit a completed Section 3.b, except for 10 CFR 35.500 uses. If the proposed user had more than one supervisor, provide the information requested in Section 3.b for each supervising individual.

Submit a completed Section 3.c for 10 CFR 35.500 uses.

Submit a completed Preceptor Attestation, except for 10 CFR 35.500 uses.

Part II. Preceptor Attestation

The Preceptor Attestation page has two sections.

The preceptor attestation is provided by either a preceptor AU or residency program director.

The attestations for training and experience requirements in 10 CFR 35.190 and 10 CFR 35.290 are found in the first section.

The second and final section requests specific information about the preceptor's authorization(s) to use licensed material, or the residency program director's attestation, and ~~in addition to~~ the preceptor AU's or residency program director's signature.

The preceptor AU or the residency program director must fill out both sections.

Note: The attestation of the proposed user's training and ability ~~competency~~ to ~~function~~ independently fulfill the radiation safety-related duties of an AU under 10 CFR 35.1900 covers the use of material permitted by 10 CFR 35.100 only. The attestation for the proposed user's training and ability ~~competency~~ to ~~function~~ independently fulfill the radiation safety related duties of an AU under 10 CFR 35.2900 will allow the individual to be authorized to use material permitted by both 10 CFR 35.100 and 10 CFR 35.200.

X. 35.300 AUTHORIZED USER - Specific Instructions and Guidance for Filling Out NRC Form 313A (AUT)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the three methods below:

Item 1. Board Certification

If the applicant is requesting AU identification for a nuclear medicine physician, radiologist, or radiation oncologist with a board certification listed under 10 CFR 35.300 on NRC's Web site, provide the requested information (i.e., a copy of the board certification~~,~~ and documentation of supervised clinical experience (complete the table in section 3.c)~~, and a completed Preceptor Attestation).~~ As indicated on the form, additional information is needed if the board certification or supervised clinical experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

If the applicant is requesting AU identification for a radiation oncologist whose board certification is not listed under 10 CFR 35.300 on NRC's Web site, provide the requested information (i.e., a copy of the board certification listed under either 10 CFR 35.400 or 10 CFR 35.600 on NRC's Web site, documentation of training and supervised work experience with unsealed materials requiring a written directive (complete the tables in Sections 3.a and 3.b), documentation of supervised clinical experience (complete the table in Section 3.c), and a completed Preceptor Attestation). As indicated on the form, additional information is needed if the board certification, training, and supervised work experience or clinical experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as
an AU.

If the applicant is requesting AU identification for a physician with a board certification issued on or before October 24, 2005, and that is listed in 10 CFR 35.57(b)(2)(ii), provide a copy of the board certification and documentation that the individual performed each use on or before October 24, 2005. As indicated on the form, additional information is needed if the board certification, training, and supervised work experience or clinical experience occurred more than 7 years ago.

Item 2. Current 10 CFR 35.300, 10 CFR 35.400, or 10 CFR 35.600 Authorized User Seeking Additional Authorization

Submit a completed Section 2.a, listing the license number and the user's current authorizations.

If the AU ~~applicant~~ is currently authorized for a subset of clinical uses under 10 CFR 35.300, submit the requested information (i.e., complete the table in Section 3.c to document the new supervised clinical case experience and, if not board certified, the completed Preceptor Attestation). As indicated on the form, additional information is needed if the clinical case experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

If the AU ~~applicant~~ is currently authorized under 10 CFR 35.490 or 10 CFR 35.690 and meets the requirements in 10 CFR 35.396, submit the requested information (i.e., documentation of training and supervised work experience with unsealed materials requiring a written directive

(complete the tables in Sections 3.a and 3.b), documentation of supervised clinical experience (complete the table in Section 3.c), and a completed Preceptor Attestation)). As indicated on the form, additional information is needed if the training and supervised work experience or clinical experience occurred more than 7 years ago. List each supervising individual by name and include the license showing the supervising individual as an AU.

Item 3. Training and Experience for Proposed Authorized Users

This section is for proposed AUs that are neither certified by a board recognized by NRC on its web site nor a board listed in 10 CFR 35.57(b)(2)(ii).

As indicated on the form, additional information is needed if the degree, training, and/or work experience was completed more than 7 years ago.

Submit a completed Section 3.a.

Submit a completed Section 3.b. List each supervising individual by name and include the license number showing the supervising individual as an AU.

Submit a completed Section 3.c for each requested authorization. List each supervising individual by name and include the license number showing the supervising individual as an AU.

Submit a completed Preceptor Attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation page has five sections.

The preceptor attestation is provided by either a preceptor AU or residency program director.

The attestations for training and experience requirements in 10 CFR 35.390, 10 CFR 35.392, and 10 CFR 35.394 are in the first section.

The attestation for supervised clinical experience is in the second section.

The attestations for ability ~~competency~~ to ~~function~~ independently fulfill the radiation safety-related duties as an AU for specific uses is in the third section.

The attestation for training and experience requirements and ability~~competency~~ to ~~function~~ independently fulfill the radiation safety duties as an AU for a radiation oncologist meeting the requirements in 10 CFR 35.396 is in the fourth section.

The fifth and final section requests specific information about the preceptor AU's authorization(s) to use licensed material~~,~~ or the residency program director's attestation, and ~~in addition to~~ the preceptor AU's or residency program director's signature.

There are seven possible categories of individuals seeking AU status under this form. Follow the instructions for the applicable category.

~~The preceptor for a proposed AU who is a nuclear medicine physician, radiologist, or radiation oncologist with a board certification listed under 10 CFR 35.390 on NRC's Web site must complete the first, second, third, and fifth sections.~~

The preceptor AU or residency program director for a proposed AU for all the uses listed in 10 CFR 35.390(b)(1)(ii)(G) who is a radiation oncologist with a board certification that is not listed under 10 CFR 35.390 on NRC's Web site or in 10 CFR 35.57(b)(2)(iii) must complete the first, second, third, and fifth sections.

The preceptor AU or residency program director for a proposed AU for 10 CFR 35.390(b)(1)(ii)(G)(iii) ~~and (iv)~~ uses who is a radiation oncologist with a board certification listed under 10 CFR 35.490 or 10 CFR 35.690 on NRC's Web site or in 10 CFR 35.57(b)(2)(iii) must complete the fourth and fifth sections.

The preceptor AU or residency program director for an AU who is not board certified and is currently authorized for a subset of clinical uses under 10 CFR 35.300 must complete the second, third, and fifth sections of this part, except for an AU meeting the criteria in 10 CFR 35.392 seeking to meet the training and experience requirements under 10 CFR 35.394.

The preceptor AU or residency program director for an AU who is not board certified and meet~~ing~~s the criteria in 10 CFR 35.392 but is seeking to meet the training and experience requirements under 10 CFR 35.394 must complete the first, second, third, and fifth sections.

The preceptor AU or residency program director for an AU currently authorized under 10 CFR 35.490 or 10 CFR 35.690 and meeting the requirements in 10 CFR 35.396 must complete the fourth, and fifth sections.

The preceptor AU or the residency program director for a proposed new AU who is not board certified must complete the first, second, third and fifth sections.

XI. 35.400 AND 35.600 AUTHORIZED USERS - Specific Instructions and Guidance for Filling Out NRC Form 313A (AUS)

See Section V, "General Instructions and Guidance for Filling out NRC Form 313A Series," for additional clarification on providing information about an individual's status on an Agreement State license, medical broad-scope license, or Master Materials License permit.

Part I. Training and Experience - select one of the three methods below:

Item 1. Board Certification

Provide the requested information (i.e., a copy of the board certification if listed on NRC's board recognition web site) for 10 CFR 35.600 uses~~,~~ and documentation of device-specific training in

the table in 3.e ~~, and for all uses, a completed Preceptor Attestation~~. As indicated on the form, additional information is needed if the board certification or device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor for new users, or either a supervising AU or an AMP authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.e if the training was provided by an AU or AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

If the individual's board certification was issued on or before October 24, 2005, and is listed in 10 CFR 35.57(b)(2)(iii), provide a copy of the board certification and documentation that the individual performed each use on or before October 24, 2005. As indicated on the form, additional information is needed if the board certification, training, and supervised work experience or clinical experience occurred more than 7 years ago.

Item 2. Current 10 CFR 35.600 Authorized User Requesting Additional Authorization for 10 CFR 35.600 Use(s) Checked Above

Provide the requested information (i.e., documentation of device-specific training (complete the table in 3.e)) and, if not board certified, a completed Preceptor Attestation in Part II. As indicated on the form, additional information is needed if the device-specific training was completed more than 7 years ago.

Device-specific training may be provided by the vendor, a supervising AU, or an AMP authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.e if the training was provided by an AU or AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Item 3. Training and Experience for Proposed Authorized Users

This section is for proposed AUs that are neither certified by a board recognized by NRC on its web site nor a board listed in 10 CFR 35.57(b)(2)(ii).

As indicated on the form, additional information is needed if the training, residency program, supervised work, and clinical experience were completed more than 7 years ago.

Submit a completed Section 3.a for each requested use.

Submit a completed Section 3.b if applying for 10 CFR 35.400 uses. However, Section 3.b does not have to be completed when only applying for use of strontium-90 for ophthalmic use. If more than one supervising AU provided the supervised work and clinical experience, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Section 3.c if only applying for use of strontium-90 for ophthalmic use. If more than one supervising AU provided the supervised clinical experience, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Section 3.d for each requested 10 CFR 35.600 use. If more than one supervising AU provided the supervised work and clinical experience, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Section 3.e for each specific 10 CFR 35.600 device for which the applicant is requesting authorization.

Device-specific training may be provided by the vendor, a supervising AU, or an AMP authorized for the requested type of use. Specific information regarding the supervising individual only needs to be provided in the table in 3.e if the training was provided by an AU or AMP. If more than one supervising individual provided the training, identify each supervising individual by name and provide his/her qualifications.

Submit a completed Preceptor Attestation in Part II.

Part II. Preceptor Attestation

The Preceptor Attestation part has five sections.

The preceptor attestation is provided by either a preceptor AU or the residency program director.

The attestation to the training and individual's ability to independently fulfill the radiation safety related duties as an authorized user ~~competency~~ for 10 CFR 35.400 uses or strontium-90 ophthalmic ~~eye applicator~~ use is in the first section.

The attestation to the training for the proposed AU for 10 CFR 35.600 uses is in the second section.

The attestation for the 10 CFR 35.600 device-specific training is in the third section.

The attestation of the individual's ability~~competency~~ to ~~function~~ independently fulfill the radiation safety-related duties as an AU for the specific 10 CFR 35.600 devices requested by the applicant is in the fourth section.

The fifth and final section requests specific information about the preceptor's authorization(s) to use licensed material, or the residency program director's attestation, and~~, in addition to~~ the preceptor AU's or residency program director's signature.

The preceptor AU or residency program director for a 10 CFR 35.400 proposed AU must fill out the first and fifth sections.

The preceptor AU or residency program director for a 10 CFR 35.600 proposed AU must fill out the second, third, fourth and fifth sections.

The preceptor AU or residency program director for an AU seeking additional 10 CFR 35.600 authorizations must complete the third, fourth, and fifth sections.

[The following redline additions to Appendix I reflect the change to 10 CFR 35.204, requiring the licensee to report breakthrough of molybdenum-99, strontium-82, and strontium-85 exceeding the limits in 10 CFR 35.204(a). The revision also reflects the changes to 10 CFR 35.24, adding an Associate Radiation Safety Officer.]

Appendix I

Typical Duties and Responsibilities of the Radiation Safety Officer and Sample Delegation of Authority

Model Radiation Safety Officer Duties and Responsibilities

The duties and responsibilities of the Radiation Safety Officer (RSO) include ensuring radiological safety and compliance with NRC and DOT regulations and the conditions of the license. Model procedures for describing the RSO's duties and responsibilities appear below. Applicants may either adopt these model procedures or develop alternative procedures to meet the requirements of 10 CFR 35.24. As a result of implementation of the EPAct, licensed material now includes accelerator-produced radioactive materials and discrete sources of Ra-226. Licensees authorized under 10 CFR 30.32(j) to produce and noncommercially transfer PET radioactive drugs to consortium members should review the model duties and responsibilities below, expanding on them as necessary to ensure radiation safety oversight of the production and transfer only to medical use consortium members.

Typically, these duties and responsibilities include ensuring the following:

- Unsafe activities involving licensed material are stopped;
- Radiation exposures are ALARA;
- Up-to-date radiation protection procedures in the daily operation of the licensee's byproduct material program are developed, distributed, and implemented;

- Possession, use, and storage of licensed material are consistent with the limitations in the license, the regulations, the SSDR certificate(s), and the manufacturer's recommendations and instructions;
- Individuals installing, relocating, maintaining, adjusting, or repairing devices containing sealed sources are trained and authorized by an NRC or Agreement State license;
- Personnel training is conducted and is commensurate with the individual's duties regarding licensed material;
- Documentation is maintained to demonstrate that individuals are not likely to receive, in 1 year, a radiation dose in excess of 10% of the allowable limits or that personnel monitoring devices are provided;
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained;
- Licensed material is properly secured;
- Documentation is maintained to demonstrate, by measurement or calculation, that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public;
- Proper authorities are notified of incidents such as loss or theft of licensed material, excess breakthrough values for Mo-99/Tc-99m or Sr-82/ Rb-82 generators, damage to or malfunction of sealed sources, and fire;
- Medical events and precursor events are investigated and reported to NRC, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken;
- Audits of the Radiation Protection Program are performed at least annually and documented;
- If violations of regulations, license conditions, or program weaknesses are identified, effective corrective actions are developed, implemented, and documented;
- Licensed material is transported, or offered for transport, in accordance with all applicable DOT requirements;
- Licensed material is disposed of properly;
- Appropriate records are maintained; ~~and~~
- An up-to-date license is maintained, and amendment and renewal requests are submitted in a timely manner~~.~~; and
- Assigning tasks and duties to an ARSO, if applicable.

Model Delegation of Authority

Memo To: Radiation Safety Officer

From: Chief Executive Officer

Subject: Delegation of Authority

You, _____, have been appointed Radiation Safety Officer and are responsible for ensuring the safe use of radiation. You are responsible for managing the Radiation Protection Program; identifying radiation protection problems; initiating, recommending, or providing corrective actions; verifying implementation of corrective actions; stopping unsafe activities; and ensuring compliance with regulations. You are hereby delegated the authority necessary to meet those responsibilities, including prohibiting the use of byproduct material by employees who do not meet the necessary requirements and shutting down operations where justified to maintain radiation safety. You are required to notify management if staff does not cooperate and does not address radiation safety issues. In addition, you are free to raise issues with the Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting radiation protection activities.

_____ _____

Signature of Management Representative Date

I accept the above responsibilities,

_____ _____

Signature of Radiation Safety Officer Date

cc: Affected department heads

Model Appointment of ARSO

Memo To: Associate Radiation Safety Officer

From: Chief Executive Officer

Radiation Safety Officer

Subject: Appointment of ARSO

You, _____, have been appointed an Associate Radiation Safety Officer and the Radiation Safety Officer with written agreement from management will assign specific oversight duties and tasks. These duties and tasks are restricted to the types of use for which you are listed on our license.

You are free to raise issues with the Nuclear Regulatory Commission at any time. It is estimated that you will spend _____ hours per week conducting Associate Radiation Safety Officer duties and tasks.

You will report to the Radiation Safety Officer, who retains responsibility for oversight of the entire radiation safety program.

_____ _____

Signature of Management Representative Date

_____ _____

Signature of Radiation Safety Officer Date

cc: Affected department heads

[The following redline additions to Appendix J reflect changes to 10 CFR 35.2, 35.24, and 35.433 adding an Associate Radiation Safety Officer and ophthalmic physicist. The revision also reflects changes to 10 CFR 35.610 requiring vendor operational and safety training for remote afterloader, teletherapy, and gamma stereotactic radiosurgery units.]

Appendix J

Model Training Program

Model procedures for describing training programs appear below. These models provide examples of topics to be chosen for training, based on the experience, duties, and previous training of trainees. The topics chosen will depend on the purpose of the training, the audience, and the state of learning (background knowledge) of the audience. These models also may be useful to identify topics for annual refresher training. Refresher training should include topics with which the individual is not involved frequently and topics that require reaffirmation. Topics for refresher training need not include review of procedures or basic knowledge that the trainee routinely uses. Applicants may either adopt these model procedures or develop an alternative program to meet NRC requirements. Guidance on requirements for training and experience for AMPs and AUs for medical use who engage in certain specialized practices is also included.

Note: With the implementation of the EPAct, the NRC now has regulatory authority for accelerator-produced radioactive material and discrete sources of Ra-226. Personnel should be provided new training on the application of the NRC requirements and license conditions to these materials when NRC's waiver of August 31, 2005, is terminated for the medical use facility. The waiver was terminated on November 30, 2007, for Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana. The appropriate NRC Regional Office should be contacted to confirm the waiver termination date for other medical use facilities.

Model Training Program for Medical and Nonmedical Uses of Radionuclides, Sealed Sources, and Medical Devices Containing Sealed Sources

Personnel will receive instruction before assuming duties with, or in the vicinity of, radioactive materials during annual refresher training, and whenever there is a significant change in duties, regulations, terms of the license, or type of radioactive material or therapy device used. Records of worker training will be maintained for at least 3 years. The training records will include the date of the instruction or training and the name(s) of the attendee(s) and instructor(s).

Training for Individuals Involved in the Medical Usage of Byproduct Material

Training for professional staff (e.g., AU, AMP, ophthalmic physicist, ANP, RSO, ARSO, nurse, dosimetrist, technologist, therapist) may contain the following elements for those who provide or are involved in the care of patients during diagnostic or therapeutic procedures, *commensurate with their duties*:

- Basic radiation biology (e.g., interaction of ionizing radiation with cells and tissues);
- Basic radiation protection to include concepts of time, distance, and shielding;
- Concept of maintaining exposure ALARA (10 CFR 20.1101);
- Risk estimates, including comparison with other health risks;
- Posting requirements (10 CFR 20.1902);
- Proper use of personnel dosimetry (when applicable);
- Access control procedures (10 CFR 20.1601, 10 CFR 20.1802);
- Proper use of radiation shielding, if used;
- Patient release procedures (10 CFR 35.75);
- Instruction in procedures for notification of the RSO and AU, when responding to patient emergencies or death, to ensure that radiation protection issues are identified and addressed in a timely manner. The intent of these procedures should in no way interfere with or be in lieu of appropriate patient care (10 CFR 19.12, 10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);
- Occupational dose limits and their significance (10 CFR 20.1201);
- Dose limits to the embryo/fetus, including instruction on declaration of pregnancy (10 CFR 20.1208);
- Worker's right to be informed of occupational radiation exposure (10 CFR 19.13);
- Each individual's obligation to report unsafe conditions to the RSO (10 CFR 19.12);
- Applicable regulations, license conditions, information notices, bulletins, etc. (10 CFR 19.12);
- Where copies of the applicable regulations, the NRC license, and its application are posted or made available for examination (10 CFR 19.11);
- Proper recordkeeping required by NRC regulations (10 CFR 19.12);
- Appropriate surveys to be conducted (10 CFR 20.1501);
- Proper calibration of required survey instruments (10 CFR 20.1501);
- Emergency procedures;
- Decontamination and release of facilities and equipment (10 CFR 20.1406, 10 CFR 30.36);
- Dose to individual members of the public (10 CFR 20.1301); and

- Licensee's operating procedures (e.g., survey requirements, instrument calibration, waste management, sealed-source leak testing) (10 CFR 35.27, 10 CFR 30.32(a)(3)).

Training for Individuals Involved in Nonmedical Usage of Byproduct Material

Training for staff working with byproduct material for nonmedical uses or animals containing byproduct material may include, as appropriate, the elements that are listed above for medical uses. Licensees authorized under 10 CFR 30.32(j) to produce PET radioactive drugs for noncommercial transfer to other medical use licensees in the consortium should also provide training on the production of PET radioactive drugs and special requirements in 10 CFR 30.32(j) and 10 CFR 30.34(j) for this activity. All training should be commensurate with the individual's duties.

Training for the Staff Directly Involved in Administration to or Care of Patients Administered Byproduct Material for which a Written Directive Is Required (Including Greater-than-30 microcuries of I-131), or Therapeutic Treatment Planning

Note: Byproduct material now includes accelerator-produced radionuclides and discrete sources of Ra-226.

In addition to the topics identified above, the following topics may be included in instruction for staff involved in the therapy treatment of patients (e.g., nursing, RSO, AMP, AU, and dosimetrist), *commensurate with their duties*:

- Leak testing of sealed sources (10 CFR 35.67 and 10 CFR 35.1000, as applicable);
- Emergency procedures (including emergency response drills) (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610, and 10 CFR 35.1000, as applicable);
- Operating instructions (10 CFR 35.27, 10 CFR 35.610, and 10 CFR 35.1000, as applicable);
- Computerized treatment planning system (10 CFR 35.657 and 10 CFR 35.1000, as applicable);
- Dosimetry protocol (10 CFR 35.630 and 10 CFR 35.1000, as applicable);
- Detailed pretreatment quality assurance checks (10 CFR 35.27, 10 CFR 35.610, and 10 CFR 35.1000, as applicable);
- Safe handling (when applicable) of the patient's dishes, linens, excretions (saliva, urine, feces), and surgical dressings that are potentially contaminated or that may contain radioactive sources (10 CFR 35.310, 10 CFR 35.410);
- Patient control procedures (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610, and 10 CFR 35.1000, as applicable);
- Visitor control procedures, such as visitors' stay times and safe lines in radiation control areas (patient's room) (10 CFR 35.310, 10 CFR 35.410, 10 CFR 35.610);

- Licensee's WD Procedures, to ensure that each administration is in accordance with the WD, patient identity is verified, and where applicable, attention is paid to correct positioning of sources and applicators to ensure that treatment is to the correct site (or, for GSR, correct positioning of the helmet) (10 CFR 35.41 and 10 CFR 35.1000, as applicable);
- Proper use of safety devices and shielding to include safe handling and shielding of dislodged sources (or, in the case of remote afterloaders, disconnected sources) (10 CFR 35.410, 10 CFR 35.610, and 10 CFR 35.1000, as applicable);
- Size and appearance of different types of sources and applicators (10 CFR 35.410, 10 CFR 35.610, and 10 CFR 35.1000, as applicable);
- Previous incidents, events, and/or accidents; and
- For remote afterloaders, teletherapy units, and GSR units, vendor training (prior to first use of a new unit or after manufacturer upgrades that affect operation and safety of the unit) and licensee operational safety training (to new staff and annually to all individuals operating the unit) that is device model-specific and includes (10 CFR 35.610):
  - Design, use, and function of the device, including safety systems and interpretation of various error codes and conditions, displays, indicators, and alarms;
  - Hands-on training in actual operation of the device under the direct supervision of an experienced user, including "dry runs" (using dummy sources) of routine patient set-up and treatment and implementation of the licensee's emergency procedures;
  - A method, such as practical examinations, to determine each trainee's competency to use the device for each type of proposed use.

Additional Training for Authorized Medical Physicists and Ophthalmic Physicists

Applicants for licenses to include AMPs and ophthalmic physicists who plan to engage in certain tasks requiring special training should ensure that the AMP is trained in the activities specific to the different types of uses listed in 10 CFR 35.51(b)(1) and 35.433 and that the ophthalmic physicist is trained in the activities specific to 10 CFR 35.433. Note, for example, that additional training is necessary for AMP planning tasks such as remote afterloader therapy, teletherapy, GSR therapy, the use of the treatment planning system that applicants contemplate using, as well as the calculation of activity of Sr-90 sources used for ophthalmic treatments and assisting the licensee in developing, implementing and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive (10 CFR 35.433). Medical physicists must also have training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system, as required in 10 CFR 35.51(c).

Additional Training for Authorized Users for Medical Uses of Byproduct Materials for Which a Written Directive Is Required

Applicants for licenses should carefully consider the type of radiation therapy that is contemplated. In addition to the training and experience requirements of 10 CFR 35.390, 10 CFR 35.394, 10 CFR 35.396, 10 CFR 35.490, 10 CFR 35.491, ~~and~~ 10 CFR 35.690, and 10 CFR 35.1000, as applicable, attention should be focused on the additional training and experience necessary for treatment planning and quality control systems, and clinical procedures. Refer to the training and experience requirements associated with specialized uses discussed in Sections 35.390, 35.490, 35.491, ~~and~~ 35.690, and 35.1000, as applicable, of 10 CFR Part 35.

Training for Ancillary Staff

For the purposes of this section, ancillary staff includes personnel engaged in janitorial and/housekeeping duties, dietary, laboratory, security, and life-safety services. The training program for ancillary staff performing duties that are likely to result in a dose in excess of 1 mSv (100 mrem) will include instruction commensurate with potential radiological health protection problems present in the work place. Alternatively, prohibitions on entry into controlled or restricted areas may be applied to ancillary personnel unless escorted by trained personnel. Topics of instruction may include the following:

- Storage, transfer, or use of radiation and/or radioactive material (10 CFR 19.12);
- Potential biological effects associated with exposure to radiation and/or radioactive material, precautions or procedures to minimize exposure, and the purposes and functions of protective devices (e.g., basic radiation protection concepts of time, distance, and shielding) (10 CFR 19.12);
- The applicable provisions of NRC regulations and licenses for the protection of personnel from exposure to radiation and/or radioactive material (e.g., posting and labeling of radioactive material) (10 CFR 19.12);
- Responsibility to report promptly to the licensee any condition that may lead to or cause a violation of NRC regulations and licenses or unnecessary exposure to radiation and/or radioactive material (e.g., notification of the RSO regarding radiation protection issues) (10 CFR 19.12);
- Appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and/or radioactive material (10 CFR 19.12);
- Radiation exposure reports that workers may request, as per 10 CFR 19.13 (10 CFR 19.12).

[Redline/strikeout revisions are shown below for several sections of Appendix L. An explanation is provided in at the beginning of each section.]

Appendix L
Model Medical Licensee Audit

[The following redline/strikeout revisions to the "Organization and Scope of Program" section of Appendix L reflect the change to 10 CFR 35.24 adding an Associate Radiation Safety Officer; the changes to 10 CFR 35.65 to prohibit bundling of single sources and clarify that calibration, transmission, or references sources may be used for medical use in accordance with the requirements of 35.500; and changes to 10 CFR 35.400, 35.500, and 35.600 requiring sources be used in accordance with the radiation safety conditions and limitations described in the Sealed Source Device Registration not as approved in the Sealed Source Device Registration. The "Organization and Scope of Program" section of Appendix L begins on page L-1 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]

Organization and Scope of Program

A. Radiation Safety Officer:

1. If the RSO was changed, was the license amended [35.13]?
2. Does the new RSO meet NRC training requirements [35.50, 35.57, 35.59]?
3. If the scope of the program expands, does the RSO have training in radiation safety, regulatory issues, and emergency procedures for the new uses [35.50(e)]?
4. Is the RSO fulfilling all responsibilities ~~duties~~ [35.24]?
5. Is the written agreement in place for a new RSO [35.24(b)]?

B. Associate Radiation Safety Officer:

1. If the ARSO was changed, was the license amended [35.13]?
2. Does the new ARSO meet NRC training requirements [35.50, 35.57, 35.59]?

3. If the scope of the program expands and the RSO intends to assign duties for the expanded program, does the ARSO have training in radiation safety, regulatory issues, and emergency procedures for the new uses [35.50(d)]?

4. Is the ARSO fulfilling all duties and tasks [35.24]?

5. Is the written appointment in place for a new ARSO [35.24(b)]?

C~~B~~. Multiple places of use? If yes, list locations.

D~~C~~. Are all locations listed on license? Includes locations of accelerator-produced radioactive materials and discrete sources of radium-226?

E~~D~~. Were annual audits performed at each location? If no, explain.

F~~E~~. Describe the scope of the program (staff size, number of procedures performed, etc.).

G~~F~~. Licensed Material:

1. Isotope, chemical form, quantity, and use as authorized? Includes accelerator-produced radioactive materials and discrete sources of radium-226?

2. Does the total amount of radioactive material possessed require financial assurance [30.35(a)]? If so, is the financial assurance adequate?

3. Calibration, transmission, and reference sources [35.65]?

   a. Sealed sources manufactured and distributed by a person licensed pursuant to 10 CFR 32.74, equivalent Agreement State regulations, or redistributed by a licensee authorized to redistribute sealed sources, and sources do not exceed 30 millicuries each [35.65(a)(1) and (2~~b~~)]?

   b. Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 15 millicuries [35.65(a)(3~~c~~)]?

   c. Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 200 microcuries or 1000 times the quantities in Appendix B of Part 30 [35.65(a)(4~~d~~)]?

   d. Technetium-99m in individual amounts as needed [35.65(a)(5~~e~~)]?

   e. The sealed sources are not combined (bundled or aggregated) to create an activity greater than the maximum activity listed above?

   f. The sources are not used for medical use except in accordance with the requirements in 35.500 [35.65(b)(1)]?

4. Unsealed materials used under 10 CFR 35.100, 35.200, and 35.300 are:

   a. Obtained from a manufacturer or preparer licensed under 10 CFR 32.72?

OR

b. Obtained from a producer of PET radioactive drugs under 10 CFR 30.32(j)?

OR

c. Prepared by a physician AU, an ANP, or an individual under the supervision of an ANP or physician AU?

OR

d. Obtained and prepared for research in accordance with 10 CFR 35.100, 10 CFR 35.200, and 10 CFR 35.300, as applicable?

5. Production of PET radioactive drugs

- Authorized under 10 CFR 30.32(j)?
- For internal use from licensee's PET radionuclide production facility as authorized in 10 CFR 35.100(b), 35.200(b), or 35.300(b)?

H~~G~~. Are the sealed sources possessed and used under 35.400, 35.500, and 35.600 approved ~~as described~~ in the Sealed Source and Device Registry (SSDR) ~~certificate in 10 CFR 32.210, 35.400, 35.500, 35.600~~? Are the sealed sources used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry? Are copies of (or access to) SSDR certificates possessed? Are manufacturers' manuals for operation and maintenance of medical devices possessed?

I~~H~~. Are there sealed sources containing accelerator-produced radioactive materials or discrete sources of radium-226 that do not have an SSDR certificate? If the sealed source is not generally licensed or exempt from licensing, seek a license amendment providing information under 10 CFR 32(g)(2) or (3).

J~~I~~. Are the actual uses of medical devices consistent with the authorized uses listed on the license?

K~~J~~. If places of use changed, was the license amended [35.13(e)]?

L~~K~~. If control of the license was transferred or bankruptcy filed, was NRC's prior consent obtained or notification made [30.34(b) and 30.34(h) respectively]?

[The following redline additions to the "Radiation Safety Program" section of Appendix L reflect a change to 10 CFR 35.12 describing information needed for 10 CFR 35.1000 medical uses. The "Radiation Safety Program" section of Appendix L appears on page L-3 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]

Radiation Safety

A. Minor changes to program [10 CFR 35.26 or, if license condition permits, changes conforming to revised licensing guidance for 10 CFR 35.1000 medical uses]?

B. Records of changes maintained for 5 years [35.2026]?

C. Content and implementation reviewed annually by the licensee [20.1101(c)]?

D. Records of reviews maintained [20.2102]?

E. Changes include addition of accelerator-produced radioactive materials or discrete sources of radium-226 to NRC-regulated Radiation Safety Program?

F. Changes include authorization to produce PET radioactive drugs for noncommercial distribution to other medical use licensees in the consortium [10 CFR 30.32(j)]?

[The following redline additions to the "Use by Authorized Individuals" section of Appendix L reflect changes to 10 CFR 35.57 including a numbering change and provision to grandfather individuals that were certified by boards listed in NRC regulations prior to March 30, 2005, and the change to 10 CFR 35.433 adding ophthalmic physicist. The "Use by Authorized Individuals" section of Appendix L begins on page L-3 of the printed copy of NUREG-1556, Vol. 9, Rev. 2]

Use by Authorized Individuals

Compliance is established by meeting at least one criterion under each category.

A. Authorized Nuclear Pharmacist [35.55, 35.57, 35.59] (***Note:*** Does not apply to facilities that are registered with FDA as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a

drug under 21 CFR 207.20(a) or registered with the State as a drug manufacturer or PET drug production facility with distribution regulated under 10 CFR 32.72):

_____ 1. Certified by specialty board?

_____ 2. Identified on NRC or Agreement State license?

_____ 3. Identified on permit issued by broad-scope or master materials licensee?

_____ 4. Identified on permit issued by master materials permittee of broad scope?

_____ 5. Identified as an ANP by a commercial nuclear pharmacy that has been authorized to identify ANPs?

_____ 6. Designated as an ANP in accordance with 10 CFR 32.72(b)(4)?

_____ 7. Meets requirements in 35.57(a)(43)?

_____ 8. Listed on facility license?

B. Authorized User [35.57, 35.59, and 35.190, 35.290, 35.390, 35.392, 35.394, 35.396, 35.490, 35.491, 35.590, 35.690]:

_____ 1. Certified by specialty board whose certification process has been recognized under 10 CFR 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a)?

_____ 2. Identified on NRC or Agreement State license?

_____ 3. Identified on permit issued by broad-scope or master materials licensee?

_____ 4. Identified on permit issued by master materials permittee of broad scope?

_____ 5. Meets requirements in 35.57(b)(2) or (b)(3)?

_____ 6. Listed on facility license?

C. Authorized Medical Physicist [35.51, 35.57, 35.59]:

_____ 1. Certified by specialty board whose certification process has been recognized under 10 CFR 35.51(a)?

_____ 2. Identified on NRC or Agreement State license?

_____ 3. Identified on permit issued by broad-scope or master materials licensee?

_____ 4. Identified on permit issued by master materials permittee of broad scope?

_____ 5. Meets requirements in 35.57(a)(3) or (a)(4)?

_____ 6. Listed on facility license?

_____ 7. If applicable, performs tasks described in 10 CFR 35.433(b)?

D. Ophthalmic Physicist

_____ 1. Meets requirements in 10 CFR 35.433(a)(2)?

_____ 2. Listed on facility license?

_____ 3. Performs tasks described in 10 CFR 35.433(b)?

E. Nonmedical use authorized users [30.33(a)(3)]:

_____ Listed on facility license for same materials and uses?

[The following redline additions to the "Notifications Since Last Audit" section of Appendix L reflect the changes to 10 CFR 35.24 and 35.433 adding an Associate Radiation Safety Officer and Ophthalmic Physicist. The "Notifications Since Last Audit" section of Appendix L appears on page L-5 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]

Notifications Since Last Audit [35.14]

A. Any Notifications since last audit [35.14]?

B. Appropriate documentation provided to NRC, for ANP, AMP, ophthalmic physicist, or AU, no later than 30 days after the individual starts work [35.14(a), 30.34(j)(4)]?

C. NRC notified within 30 days after: AU, ANP, AMP, ophthalmic physicist, or RSO/ARSO stops work or changes name; licensee's mailing address changes; licensee's name changes without a transfer of control of the license; or licensee has added to or changed an area of use for 10 CFR 35.100 or 35.200 use, if the change does not include addition or relocation of either an area where PET radionuclides are produced or a radionuclide delivery line from a PET radionuclide production area; the licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number [35.14(b)]?

[The following redline/strikeout revisions to the "Training, Retraining and Instructions to Workers" section of Appendix L reflect the change to 10 CFR 35.610 requiring vendor operational and safety training to be provided prior to the first use of a new or upgraded remote afterloader, teletherapy, or gamma stereotactic radiosurgery unit. The "Training, Retraining, and

Instructions to Workers" section of Appendix L begins on page L-5 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]

Training, Retraining, and Instructions to Workers

A. Have workers been provided with required instructions [19.12, 35.27, 35.310, 35.410, 35.610]?

B. Have workers been informed of NRC's regulatory authority for accelerator-produced radioactive materials and discrete sources of radium-226?

C. Is the individual's understanding of current procedures and regulations adequate?

D. Is the training program implemented?

1. Operating procedures [35.27, 35.310, 35.410, 35.610]?
2. Emergency procedures [35.27, 35.310, 35.410, 35.610]?
3. Periodic training required and implemented [35.310, 35.410, 35.610]?
4. Vendor operational and safety training provided prior to first patient treatment of a new or upgraded remote afterloader, teletherapy, or gamma stereotactic radiosurgery unit [35.610]?
5~~4~~. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed and was refresher training provided, as needed [19.12]?
6~~5~~. Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives, as appropriate [35.27]?
7~~6~~. Are initial and periodic training records maintained for each individual [35.2310]?
8~~7~~. Briefly describe training program.

E. Do additional therapy device instructions/training include:

1. Unit operation, inspection, associated equipment, survey instruments?
2. License conditions applicable to the use of the unit?
3. Emergency drills [35.610]?

F. 10 CFR Part 20 – Are workers cognizant of requirements for:

1. Radiation Safety Program [35.24, 35.26, 20.1101]?
2. Annual dose limits [20.1201, 20.1301, 20.1302]?
3. NRC Forms 4 and 5?

4. 10% monitoring threshold [20.1502]?
5. Dose limits to embryo/fetus and declared pregnant worker [20.1208]?
6. “Grave Danger” Posting [20.1902(c)]?
7. Procedures for opening packages [20.1906]?

G. Is supervision of individuals by AU and/or ANP in accordance with 10 CFR 35.27?

[The following redline/strikeout revisions to the “Dose or Dosage Measuring Equipment” section of Appendix L reflect the change to 10 CFR 35.204 requiring the licensee to report breakthrough of molybdenum-99, strontium-82, and strontium-85 exceeding the limits in 10 CFR 35.204(a). The “Dosage or Dosage Measuring Equipment” section of Appendix L begins on page L-7 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]

Dose or Dosage Measuring Equipment

A. Possession, use, and calibration of instruments to measure activities of unsealed radionuclides [35.60] or PET radioactive drugs produced by licensee [30.34(j)]:

1. Types of equipment listed?
2. Approved procedures for use of instrumentation followed?
3. Constancy, accuracy, linearity, and geometry dependence tests performed in accordance with nationally recognized standards or the manufacturer’s instructions?
4. Instrument repaired or replaced or dosages mathematically corrected, as required, when tests do not meet the performance objectives provided in the nationally recognized standard or manufacturer’s instructions (e.g., ±10%)?
5. Records maintained and include required information [35.2060]?

B. Determination of dosages of unsealed byproduct material [35.63, 30.34(j)]?

1. Each dosage determined and recorded prior to medical use [35.63(a)]? Or transfer [30.34(j)]?
2. Measurement of unit dosages of photon- or beta-emitting radionuclides made either by direct measurement or by decay correction [35.63(b), 30.34(j)(2)(ii)]?
3. Measurement of unit dosage of alpha-emitting radionuclide by decay correction of the activity provided by the producer licensed in accordance with 10 CFR 32.72 or 30.32(j)?

4. For other than unit dosages of photon- or beta-emitting radionuclides, measurement made by direct measurement of radioactivity or by combination of radioactivity or volumetric measurement and calculation [35.63(c), 30.34(j)(2)(ii)]?

5. For other than unit dosages of alpha-emitting radionuclide, measurement made by combination using the activity provided by the producer licensed in accordance with 10 CFR 32.72, or 30.32(j) volumetric measurement, and calculation [35.63(c)]?

C. Licensee uses generators?

1. Each~~First~~ eluate ~~after receipt~~ tested for Mo-99 breakthrough [35.204(b)]?

2. No radiopharmaceuticals administered with Mo-99 concentrations over 0.15 µCi per mCi of Tc-99m [35.204(a)(1)]?

3. Before first patient use of the day~~First~~ eluate ~~after receipt~~ tested for strontium-82 and strontium-85 when eluting rubidium-82 [35.204(c)]?

4. No radiopharmaceuticals administered with strontium-82 concentrations over 0.02 µCi per mCi of rubidium-82 or strontium-85 concentrations over 0.2 µCi per mCi of rubidium-82 [35.204(a)(2)]?

5. Each measurement that exceeds the limits in paragraph 2 or 4 above reported to NRC and distributor of the generator in accordance with § 35.3204?

6~~5~~. Records maintained [35.2204]?

D. Dosimetry Equipment [35.630]:

1. Calibrated system available for use [35.630(a)]?

2. Calibrated by NIST or an AAPM-accredited lab within previous 2 years and after servicing [35.630(a)(1)] OR calibrated by intercomparison per 10 CFR 35.630(a)(2)?

3. Calibrated within the previous 4 years [35.630(a)(2)]?

4. Licensee has available for use a dosimetry system for spot-check measurements [35.630(b)]?

5. Record of each calibration, intercomparison, and comparison maintained [35.2630]?

[The following redline/strikeout revisions to the "Teletherapy and Gamma Stereotactic Radiosurgery" section of Appendix L reflect the change to 10 CFR 35.655 updating the intervals at which full-inspection servicing is required for teletherapy and gamma stereotactic radiosurgery units. The "Teletherapy and Gamma Stereotactic Radiosurgery Servicing" section of Appendix L appears on page L-13 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]

Teletherapy and Gamma Stereotactic Radiosurgery Full-inspection Servicing

A. Full i~~I~~nspection and servicing performed during source replacement at intervals not to exceed 5 years for each teletherapy unit and not to exceed 7 years for each gamma stereotactic radiosurgery unit [35.655(a)]?

B. Needed service arranged for as identified during the inspection?

C. Service performed by persons specifically authorized to do so [35.655(b)]?

[The following redline/strikeout revisions to the "Notification and Reports" section of Appendix L reflect the change to 10 CFR 35.204, requiring the licensee to report breakthrough of molybdenum-99, strontium-82, and strontium-85 exceeding the limits in 10 CFR 35.204(a). The "Notifications and Reports" section of Appendix L appears on page L-19 of the printed copy of NUREG-1556, Vol. 9, Rev. 2.]

Notification and Reports (this now includes notifications and reports for accelerator-produced radioactive materials and discrete sources of radium-226)

A. In compliance with 10 CFR 19.13, and 10 CFR 30.50 (reports to individuals, public and occupational, monitored to show compliance with Part 20)?

B. In compliance with 10 CFR 20.2201, and 10 CFR 30.50 (theft or loss)?

C. In compliance with 10 CFR 20.2202, and 10 CFR 30.50 (incidents)?

D. In compliance with 10 CFR 20.2203, and 10 CFR 30.50 (overexposure and high radiation levels)?

E. In compliance with 10 CFR 35.204(e) (generator eluate that exceeds breakthrough levels)?

~~F~~E. Aware of NRC Operations Center telephone number?

~~F~~G. In compliance with 10 CFR 20.2203 (constraint on air emissions)

[The following redline/strikeout revisions to Appendix S reflect the change to 10 CFR 35.40 adding separate written directive requirements for permanent implant brachytherapy.]

Appendix S

Model Procedures for Developing, Maintaining, and Implementing Written Directives

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, the requirements for written directives and procedures to assure that administrations are in accordance with these written directives also apply to the medical use of accelerator-produced radioactive materials and discrete sources of radium-226 after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

This model provides acceptable procedures for administrations that require written directives (WDs). Applicants may either adopt this model procedure or develop their own procedure to meet the requirements of 10 CFR 35.40 and 10 CFR 35.41.

Written Directive Procedures

This model provides guidance to licensees and applicants for developing, maintaining, and implementing procedures for administrations that require WDs. This model does not restrict the use of other guidance in developing, implementing, and maintaining written procedures for administrations requiring a WD. Such procedures are to provide high confidence that the objectives specified in 10 CFR 35.41 will be met.

The WD must be prepared for any administration of I-131 sodium iodide greater than 1.11 MBq (30 µCi), any therapeutic dosage of a radiopharmaceutical, and any therapeutic dose of radiation from byproduct material. The WD must contain the information described in 10 CFR 35.40 and be retained in accordance with 10 CFR 35.2040.

Discussion

The administration of radioactive materials can be a complex process for many types of diagnostic and therapeutic procedures in nuclear medicine or radiation oncology departments. A number of individuals may be involved in the delivery process. For example, in an oncology department, when the authorized user (AU) prescribes a teletherapy treatment, the delivery process may involve a team of medical professionals such as an authorized medical physicist (AMP), a dosimetrist, and a radiation therapist. Treatment planning may involve a number of measurements, calculations, computer-generated treatment plans, patient simulations, portal film verifications, and beam-modifying devices to deliver the prescribed dose. Therefore, instructions must be clearly communicated to the professional team members with constant attention devoted to detail during the treatment process. Complicated processes of this nature require good planning and clear, understandable procedures. To help ensure that all personnel involved in the treatment fully understand instructions in the WD or treatment plan, the licensee should instruct all workers to seek guidance if they do not understand how to carry out the WD. Specifically, workers should ask if they have any questions about what to do or how it should be done before administration, rather than continuing a procedure when there is any doubt. Licensees should also consider verification of WDs or treatment plans by at least one qualified person (e.g., an oncology physician, AMP, nuclear medicine technologist, or radiation therapist), preferably other than the individual who prepared the dose, the dosage, or the treatment plan.

The administration of radioactive materials, including the administration of accelerator-produced radioactive materials and discrete sources of radium-226, can involve a number of treatment modalities (e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery (GSR), and future emerging technologies). For each such modality for which 10 CFR 35.40 requires, or would require, a WD (as defined in 10 CFR 35.2), the licensee should develop, implement, and maintain written procedures to meet the requirements and/or objectives of 10 CFR 35.40, 35.41, and 35.63, outlined below:

- Have an AU date and sign a WD, prior to the administration, that includes the information in 10 CFR 35.40(b), including the name of the patient or human research subject;
- Verify the identity of the patient or human research subject prior to each administration;
- Verify that the administration is in accordance with the treatment plan, if applicable, and the WD;
- Check both manual and computer-generated dose calculations;

- Verify that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices authorized by 10 CFR 35.60 or 35.1000;
- Determine if a medical event, as defined in 35.3045 has occurred;
- Determine for permanent implant brachytherapy, within 60 calendar days from the date of implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implant portion of the written directive; and
- Determine and record the activity of the radiopharmaceutical dosage or radiation dose before medical use.

The following procedures are provided as assistance in meeting the above objectives.

Procedures for Any Therapeutic Dose or Dosage of a Radionuclide, Including Doses or Dosages of Accelerator-Produced Radioactive Materials and Discrete Sources of Radium-226, or Any Dosage of Quantities Greater than 30 Microcuries of I-131 Sodium Iodide

Develop, implement, and maintain the following procedures to meet the objectives of 10 CFR 35.40 and 10 CFR 35.41:

- An AU must date and sign a WD prior to the administration of any dose or dosage. Written directives may be maintained in patients' charts.
- Prior to administering a dose or dosage, the identity of a patient or human research subject will be positively verified as the individual named in the WD. Examples of positive patient identity verification include examining the patient's ID bracelet, hospital ID card, driver's license, or Social Security card. Asking or calling the patient's name does not constitute positive patient identity verification.
- The specific details of the administration will be verified, including the dose or dosage, in accordance with the WD or treatment plan. All components of the WD (radionuclide, total dose or dosage, etc.) will be confirmed by the person administering the dose or dosage to verify agreement with the WD. Appropriate verification methods include: measuring the activity in the dose calibrator, checking the serial number of the sealed sources behind an appropriate shield, using color-coded sealed sources, or using clearly marked storage locations.

Additional Procedures for Sealed Therapeutic Sources and Devices Containing Sealed Therapeutic Sources (this now includes sources containing accelerator-produced radioactive materials or discrete sources of radium-226)

Licensees are required under 10 CFR 35.40 and 10 CFR 35.41 to have WDs for certain administrations of doses and to have procedures for administrations for which a WD is required. Model procedures for meeting these requirements appear below.

A. To ensure that the dose is delivered in accordance with the WD, the AU (and the neurosurgeon for GSR therapy) must date and sign (indicating approval of) the treatment

plan that provides sufficient information and direction to meet the objectives of the WD.

B. For sealed sources inserted into the patient's body, radiographs or other comparable images (e.g., computerized tomography) will be used as the basis for verifying the position of the nonradioactive dummy sources and calculating the administered dose before administration. However, for some brachytherapy procedures, the use of various fixed geometry applicators (e.g., appliances or templates) may be required to establish the location of the temporary sources and to calculate the exposure time (or, equivalently, the total dose) required to administer the prescribed brachytherapy treatment. In these cases, radiographs or other comparable images may not be necessary, provided the position of the sources is known prior to insertion of the radioactive sources and calculation of the exposure time (or, equivalently, the total dose).

C. Dose calculations will be checked before administering the prescribed therapy dose. An AU or a qualified person under the supervision of an AU (e.g., an AMP, oncology physician, dosimetrist, or radiation therapist), preferably one who did not make the original calculations, will check the dose calculations. Methods for checking the calculations include the following:

1. For computer-generated dose calculations, examining the computer printout to verify that correct input data for the patient was used in the calculations (e.g., source strength and positions).
2. For computer-generated dose calculations entered into the therapy console, verifying correct transfer of data from the computer (e.g., channel numbers, source positions, and treatment times).
3. For manually-generated dose calculations, verifying:
    a. No arithmetical errors;
    b. Appropriate transfer of data from the WD, treatment plan, tables, and graphs;
    c. Appropriate use of nomograms (when applicable); and
    d. Appropriate use of all pertinent data in the calculations.

    The therapy dose will be manually calculated to a single key point and the results compared to the computer-generated dose calculations. If the manual dose calculations are performed using computer-generated outputs (or vice versa), verify the correct output from one type of calculation (e.g., computer) to be used as an input in another type of calculation (e.g., manual). Parameters such as the transmission factors for wedges and applicators and the source strength of the sealed source used in the dose calculations will be checked.

D. After implantation but before completion of the procedure or the patient leaves the post-treatment recovery area, record in the WD: For temporary implants, as required by 10 CFR 35.40(b)(7)(ii),~~record in the WD~~the radionuclide, treatment site, number of sources, and total source strength and exposure time (or the total dose).~~;~~ the signature of an AU authorized for 10 CFR 35.400 uses for manual brachytherapy involving 35.400 materials or the signature of an authorized user for low, medium, and pulsed dose rate remote after loaders under 35.600 for low, medium, and pulsed dose rate remote after loaders; and the date. ~~proceedures involving~~; For permanent implants, as required by 10 CFR 35.40 (b)(6)(ii), the treatment site, the number of sources implanted, the total source strength implanted, the signature of an AU for §35.400 uses for manual brachytherapy, and the date. ~~For example, after insertion of permanent implant brachytherapy sources, an AU should promptly record the actual number of radioactive sources implanted and the total source strength.~~ The WD may be maintained in the patient's chart.

E. Acceptance testing will be performed by a qualified person (e.g., an AMP) on each treatment planning or dose calculating computer program that could be used for dose calculations. Acceptance testing will be performed before the first use of a treatment planning or dose calculating computer program for therapy dose calculations. Each treatment planning or dose calculating computer program will be assessed based on specific needs and applications. A check of the acceptance testing will also be performed after each source replacement or when spot check measurements indicate that the source output differs by more than 5% from the output obtained at the last full calibration corrected mathematically for radioactive decay.

F. Independent checks on full calibration measurements will be performed. The independent check will include an output measurement for a single specified set of exposure conditions and will be performed within 30 days following the full calibration measurements. The independent check will be performed by either:

1. An individual who did not perform the full calibration (the individual will meet the requirements specified in 10 CFR 35.51) using a dosimetry system other than the one that was used during the full calibration (the dosimetry system will meet the requirements specified in 10 CFR 35.630); or

2. An AMP (or an oncology physician, dosimetrist, or radiation therapist who has been properly instructed) using a thermoluminescence dosimetry service available by mail that is designed for confirming therapy doses and that is accurate within 5%.

G. For GSR, particular emphasis will be directed on verifying that the stereoscopic frame coordinates on the patient's skull match those of the treatment plan.

H. A physical measurement of the teletherapy output will be made under applicable conditions prior to administration of the first teletherapy fractional dose, if the patient's

treatment plan includes: (1) field sizes or treatment distances that fall outside the range of those measured in the most recent full calibration; or (2) transmission factors for beam-modifying devices (except nonrecastable and recastable blocks, bolus and compensator materials, and split-beam blocking devices) not measured in the most recent full calibration measurement.

I. A weekly chart check will be performed by a qualified person under the supervision of an AU (e.g., an AMP, dosimetrist, oncology physician, or radiation therapist) to detect mistakes (e.g., arithmetical errors, miscalculations, or incorrect transfer of data) that may have occurred in the daily and cumulative dose administrations from all treatment fields or in connection with any changes in the WD or treatment plan.

J. Treatment planning computer systems using removable media to store each patient's treatment parameters for direct transfer to the treatment system will have each card labeled with the corresponding patient's name and identification number. Such media may be reused (and must be relabeled) in accordance with the manufacturer's instructions.

Review of Administrations Requiring a Written Directive (this now includes administrations of accelerator-produced radioactive materials or discrete sources of radium-226)

Conduct periodic reviews of each applicable program area (e.g., radiopharmaceutical therapy, high-dose-rate brachytherapy, implant brachytherapy, teletherapy, gamma stereotactic radiosurgery, and emerging technologies). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and be representative of each treatment modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy and gamma stereotactic radiosurgery).

If feasible, the persons conducting the review should not review their own work. If this is not possible, two people should work together as a team to conduct the review of that work. Regularly review the findings of the periodic reviews to ensure that the procedures for administrations requiring a WD are effective.

As required by 10 CFR 35.41, a determination will be made as to whether the administered radiopharmaceutical dosage or radiation dose was in accordance with the WD or treatment plan, as applicable. When deviations from the WD are found, the cause of each deviation and the action required to prevent recurrence should be identified.

Reports of Medical Events (this now includes reports of events involving accelerator-produced radioactive materials or discrete sources of radium-226)

Notify by telephone the NRC Operations Center[1] no later than the next calendar day after discovery of a medical event and submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after the discovery of the medical event, as required by 10 CFR 35.3045. Also notify the referring physician and the patient as required by 10 CFR 35.3045.

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1[1]The commercial telephone number of the NRC Operations Center is (301) 816-5100. The Center will accept collect calls.

[The following redline/strikeout revision to Appendix X reflects the change to 10 CFR 35.655 updating the intervals at which full-inspection servicing is required for teletherapy and gamma stereotactic radiosurgery units.]

Appendix X

Recordkeeping Requirements

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, the recordkeeping requirements below also apply to the medical uses of accelerator-produced radioactive materials and discrete sources of radium-226 after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

Table X.1 Typical Records and Retention Times

Record	Survey Requirement	Recordkeeping Requirement	Retention Period
Results of surveys and calibrations	20.1501; 20.1906(b)	20.2103(a)	3 years
Results of surveys to determine dose from external sources		20.2103(b)(1)	duration of license
Results of measurements and calculations used to determine individual intakes		20.2103(b)(2)	duration of license
Results of air samplings, surveys, and bioassays	20.1703(c)(1); 20.1703(c)(2)	20.2103(b)(3)	duration of license
Results of measurements and calculations used to evaluate the release of radioactive effluents to the environment		20.2103(b)(4)	duration of license
Determination of prior occupational dose		20.2104	duration of license
Planned special exposure	20.1206	20.2105	duration of license
Individual monitoring results	20.1502	20.2106	duration of license

Table X.1 Typical Records and Retention Times

Record	Survey Requirement	Recordkeeping Requirement	Retention Period
Dose to individual members of the public	20.1301	20.2107	duration of license
Waste disposal	20.2002; 20.2003; 20.2004; 20.2005	20.2108	duration of license
Records of receipt of byproduct material		30.51(a)(1)	duration of possession and 3 years after transfer
Records of transfer of byproduct material		30.51(a)(2)	3 years after transfer
Records of disposal of byproduct material		30.51(a)(3)	duration of license

Table X.1 Typical Records and Retention Times (continued)

Record	Survey Requirement	Recordkeeping Requirement	Retention Period
Authority and responsibilities of Radiation Protection Program	35.24(a)	35.2024	5 years
Radiation Protection Program changes	35.26(a)	35.2026	5 years
Written directives	35.40	35.2040	3 years
Procedures for administrations requiring a written directive	35.41(a)	35.2041	duration of license
Calibrations of instruments used to measure activity of unsealed byproduct material	35.60	35.2060	3 years
Radiation survey instrument calibrations	35.61	35.2061	3 years
Dosages of unsealed byproduct material for medical use	35.63	35.2063	3 years
Leak tests and inventory of sealed sources and brachytherapy sources	35.67(b)	35.2067	3 years
Surveys for ambient radiation exposure rate	35.70	35.2070	3 years

Table X.1 Typical Records and Retention Times

Record	Survey Requirement	Recordkeeping Requirement	Retention Period
Release of individuals containing unsealed byproduct material or implants containing byproduct material	35.75	35.2075	3 years
Mobile medical services	35.80(a)(1)	35.2080	3 years
Decay-in-storage	35.92	35.2092	3 years
Molybdenum-99 or strontium-82 or strontium-85 concentrations	35.204(b)	35.2204	3 years
Safety instruction	35.310; 35.410; 35.610	35.2310	3 years
Surveys after source implant and removal	35.404; 35.604	35.2404	3 years
Brachytherapy source accountability	35.406	35.2406	3 years
Calibration measurements of brachytherapy sources	35.432	35.2432	3 years
Decay of strontium-90 sources for ophthalmic treatments	35.433	35.2433	life of source
Installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	35.604	35.2605	3 years
Safety procedures	35.610(a)(4); 35.610(d)(2)	35.2610	duration of possession of specified equipment
Dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	35.630	35.2630	duration of license
Teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations	35.632; 35.633; 35.635	35.2632	3 years
Periodic spot-checks of teletherapy units	35.642	35.2642	3 years

Table X.1 Typical Records and Retention Times

Record	Survey Requirement	Recordkeeping Requirement	Retention Period
Periodic spot-checks of remote afterloader units	35.643	35.6243	3 years
Periodic spot-checks of gamma stereotactic radiosurgery units	35.645	35.6245	3 years
Additional technical requirements for mobile remote afterloader units	35.647	35.6247	3 years
Surveys of therapeutic treatment units	35.652	35.2652	duration of use of unit
Full-inspection servicing ~~5-year inspection~~ for teletherapy and gamma stereotactic radiosurgery units	35.655	35.2655	duration of use of unit

[The following redline addition to Appendix Y reflects the change to 10 CFR 35.204, requiring the licensee to report breakthrough of molybdenum-99, strontium-82, and strontium-85 exceeding the limits in 10 CFR 35.204(a).]

Appendix Y

1Reporting Requirements

With the implementation of the EPAct, the NRC now has regulatory authority over accelerator-produced radioactive materials and discrete sources of radium-226. Therefore, the reporting requirements below also apply to the medical uses of accelerator-produced radioactive materials and discrete sources of radium-226 after NRC's waiver of August 31, 2005, is terminated for medical use facilities. The NRC waiver that applied to Government agencies, Federally recognized Indian tribes, Delaware, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Indiana, Wyoming, and Montana was terminated on November 30, 2007. The NRC Regional Offices should be contacted to confirm the waiver termination date for other medical use facilities.

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Table Y.1 Typical NRC Notifications and/or Reports

Event	Telephone Notification	Written Report	Regulatory Requirement
Reports to individual workers	None	annually	10 CFR 19.13(b)
Reports to former individual workers	None	upon request	10 CFR 19.13(c)
Notification of special circumstances to individuals	None	30 days	10 CFR 19.13(d)
Reports to worker terminating employment	None	upon request	10 CFR 19.13(e)
Theft or loss of material	immediate	30 days	10 CFR 20.2201(a)(1)(i)
Whole body dose greater than 0.25 Sv (25 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(i), 10 CFR 20.2203 (a)
Extremity dose greater than 2.5 Sv (250 rems)	immediate	30 days	10 CFR 20.2202(a)(1)(iii), 10 CFR 20.2203 (a)
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(i), 10 CFR 20.2203 (a)

Table Y.1 Typical NRC Notifications and/or Reports

Event	Telephone Notification	Written Report	Regulatory Requirement
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	10 CFR 20.2202(b)(1)(iii), 10 CFR 20.2203(a)
Doses in excess of specified criteria	None	30 days	10 CFR 20.2203(a)(2)
Levels of radiation or concentrations of radioactive material in excess of specified criteria	None	30 days	10 CFR 20.2203(a)(3)
Planned special exposures	None	30 days	10 CFR 20.2204
Report to individuals of exceeding dose limits	None	30 days	10 CFR 20.2205
Report of individual monitoring	None	annually	10 CFR 20.2206
Defect in equipment that could create a substantial safety hazard	2 days	30 days	10 CFR 21.21(d)(3)(i)
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	immediate	30 days	10 CFR 30.50(a)
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	10 CFR 30.50(b)(2)
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	10 CFR 30.50(b)(4)
Licensee permits individual to work as AU, ANP, or AMP	None	30 days	10 CFR 35.14(a)

Table Y.1 Typical NRC Notifications and/or Reports

Event	Telephone Notification	Written Report	Regulatory Requirement
AU, ANP, or AMP discontinues performance of duties under license or has a name change	None	30 days	10 CFR 35.14(b)(1)
Licensee's mailing address changes	None	30 days	10 CFR 35.14(b)(2)
Licensee's name changes without constituting a transfer of control	None	30 days	10 CFR 35.14(b)(3)
Licensee adds or changes areas of 10 CFR 35.100 or 35.200 use of byproduct material identified in application or license if the change or addition did not involve movement of a PET radionuclide production facility or transfer line from a PET radionuclide production facility	None	30 days	10 CFR 35.14(b)(4)
Medical event	1 day	15 days	10 CFR 35.3045
Dose to embryo or nursing child	1 day	15 days	10 CFR 35.3047
Leaking source	none	5 days	10 CFR 35.3067
Eluate exceeding permissible molybdenum-99, strontium-82, or strontium-85 concentrations	7 days	30 days	10 CFR 35.3204

Note: Telephone notifications shall be made to the NRC Operations Center at 301-951-0550, except as noted.